Exploring the Current Management Paradigm for Patients with Metastatic Triple-Negative Breast Cancer

A CME/MOC-Accredited Live Webinar

In Partnership with Florida Cancer Specialists & Research Institute

Monday, November 18, 2024
5:00 PM – 6:00 PM ET

Faculty

Priyanka Sharma, MD
Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Faculty

Priyanka Sharma, MD
Frank B Tyler Professor in Cancer Research
Division of Medical Oncology, Department of Internal Medicine
Co-Program Leader
Drug Discovery, Delivery and Experimental Therapeutics Program
The University of Kansas Cancer Center
Westwood, Kansas

Sara M Tolaney, MD, MPH
Chief, Division of Breast Oncology
Dana-Farber Cancer Institute
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

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Commercial Support

This activity is supported by an educational grant from Gilead Sciences Inc.

Dr Love — Disclosures

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Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

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Consulting Agreements	AstraZeneca Pharmaceuticals LP, Genzyme Corporation, Gilead Sciences Inc, GSK, Merck, Novartis, Pfizer Inc, Sanofi
Contracted Research	Gilead Sciences Inc, Merck, Novartis
Stock Options/Stock — Public Company	Amgen Inc, Janssen Biotech Inc, Johnson & Johnson Pharmaceuticals, Sanofi

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Dr Tolaney — Disclosures

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Contracted Research	AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, Daiichi Sankyo Inc, Eisai Inc, Exelixis Inc, Genentech, a member of the Roche Group, Gilead Sciences Inc, Lilly, Menarini Group, Merck, NanoString Technologies, Novartis, OncoPep, Pfizer Inc, Seagen Inc, Stemline Therapeutics Inc
Travel Support	BioNTech SE, Gilead Sciences Inc, Jazz Pharmaceuticals Inc, Lilly, Pfizer Inc, Sanofi

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This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.

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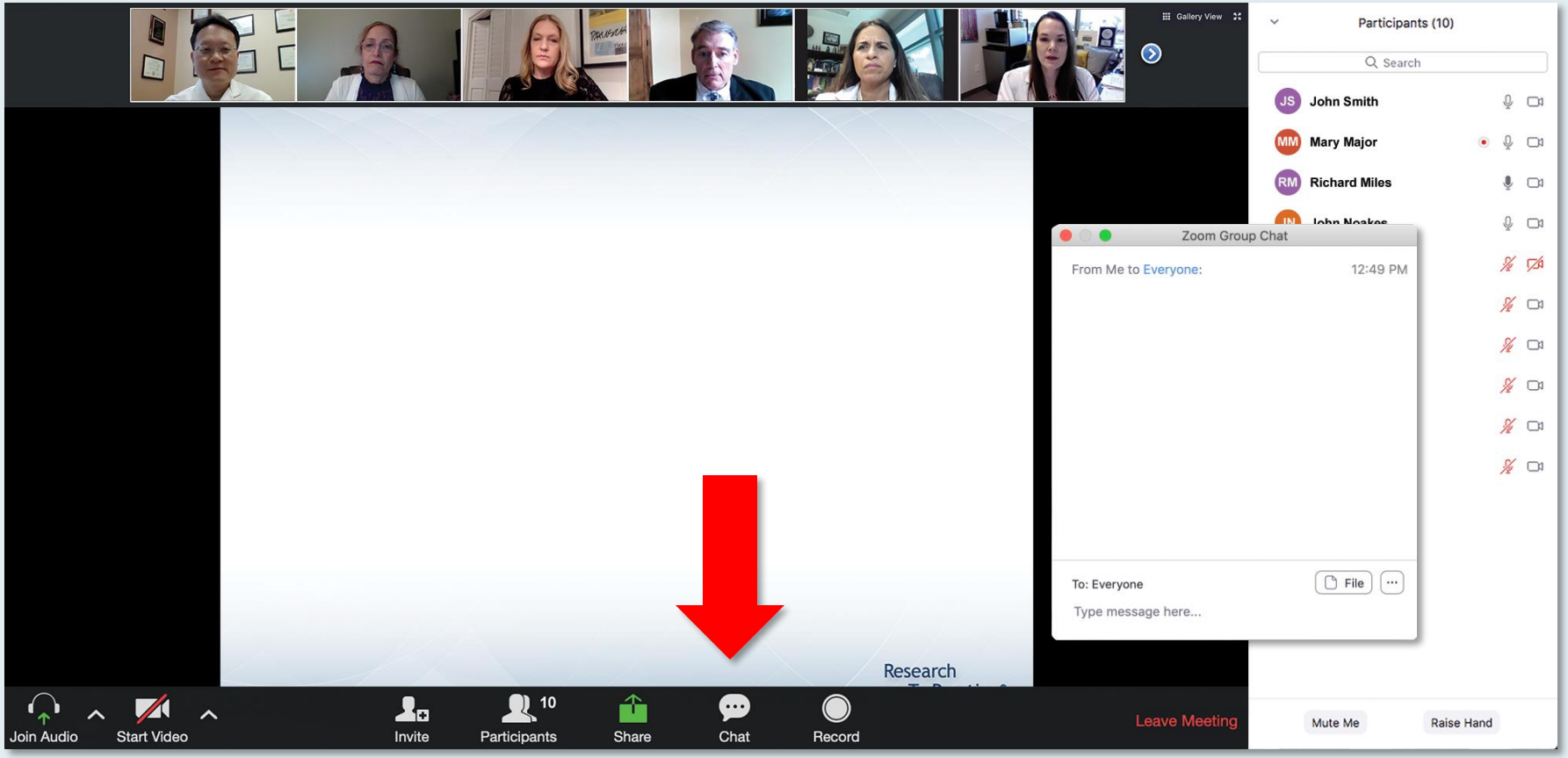
We Encourage Clinicians in Practice to Submit Questions



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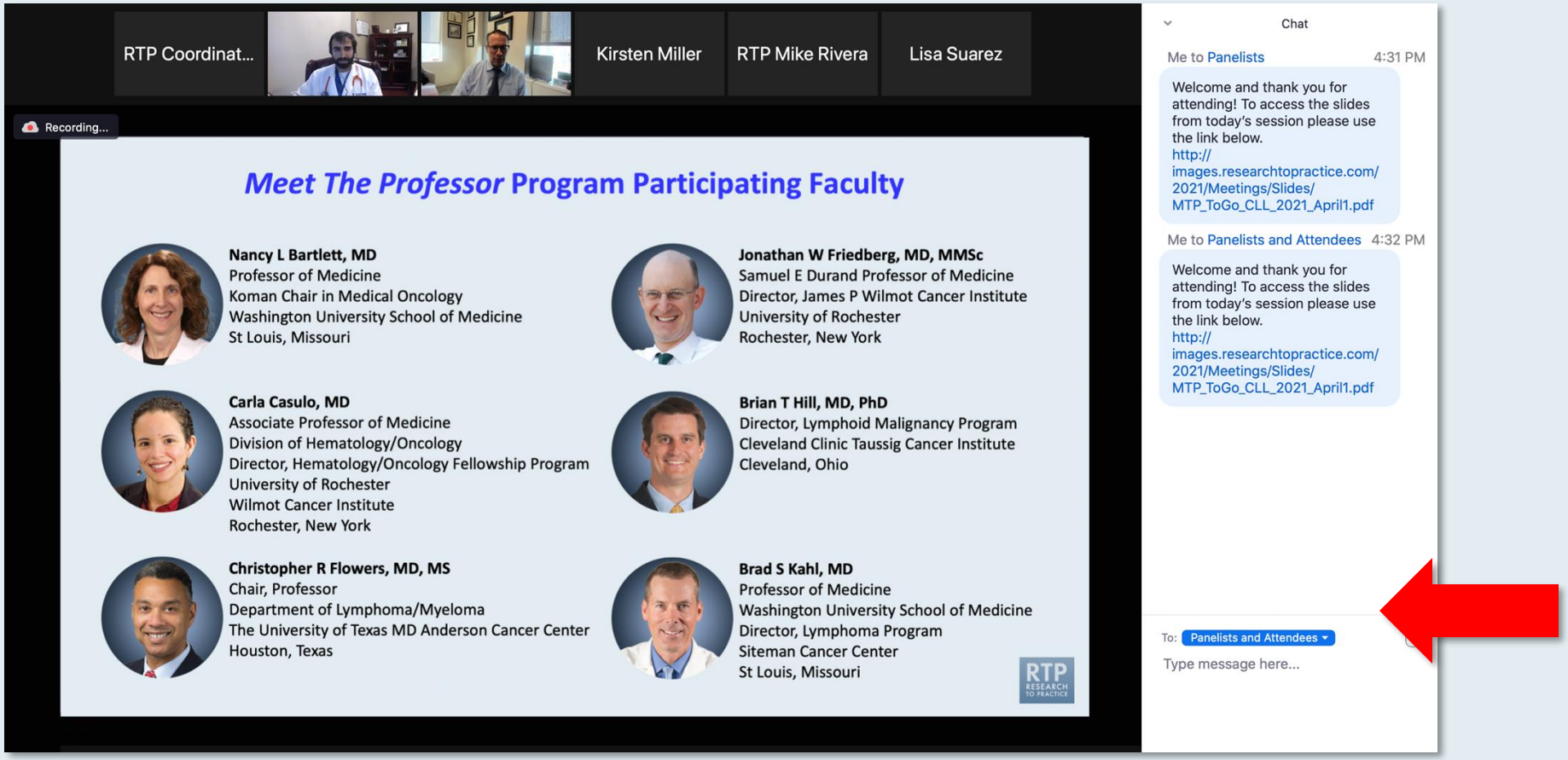
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



Drag the white line above the submission box up to create more space for your message.

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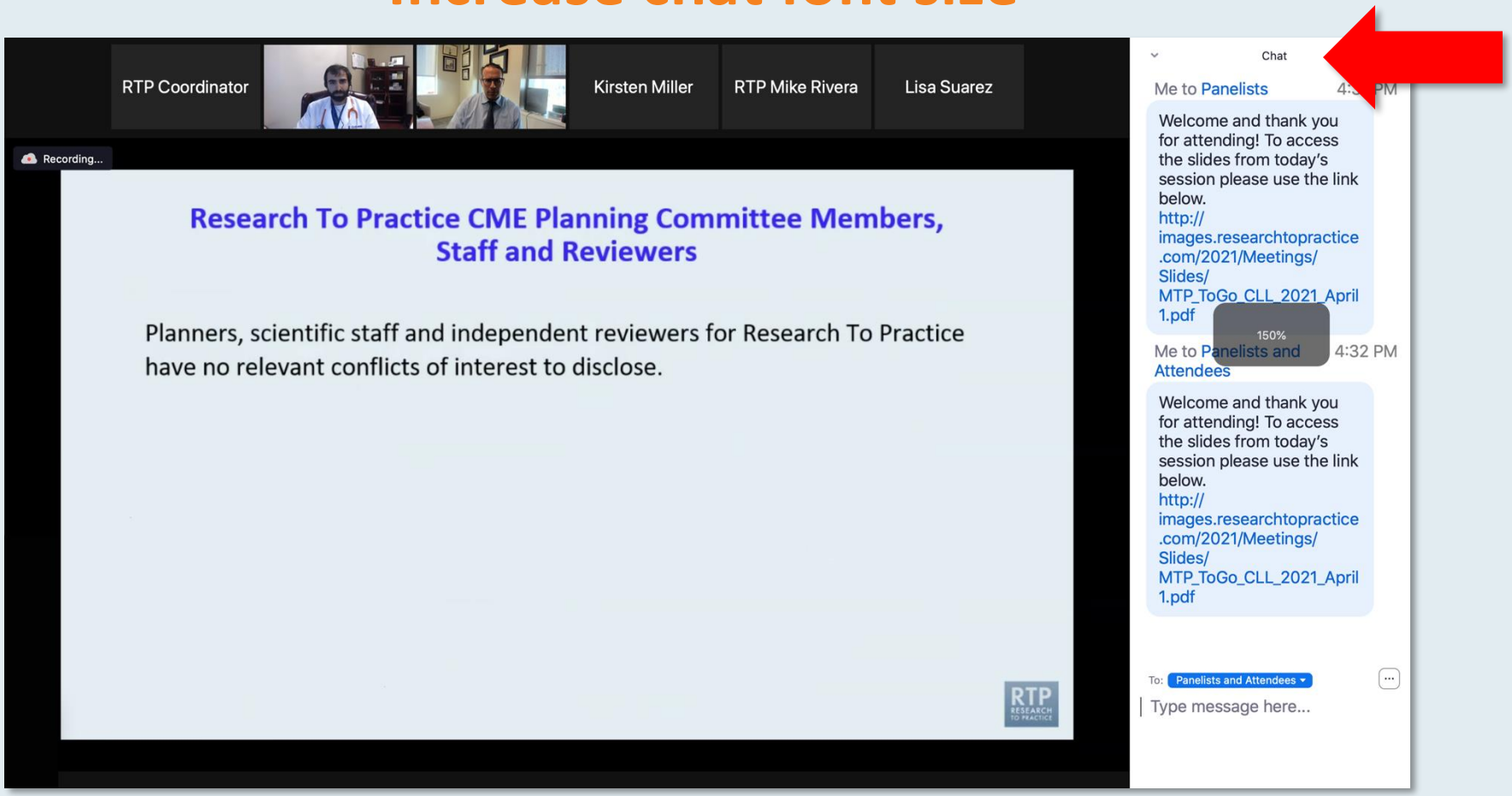
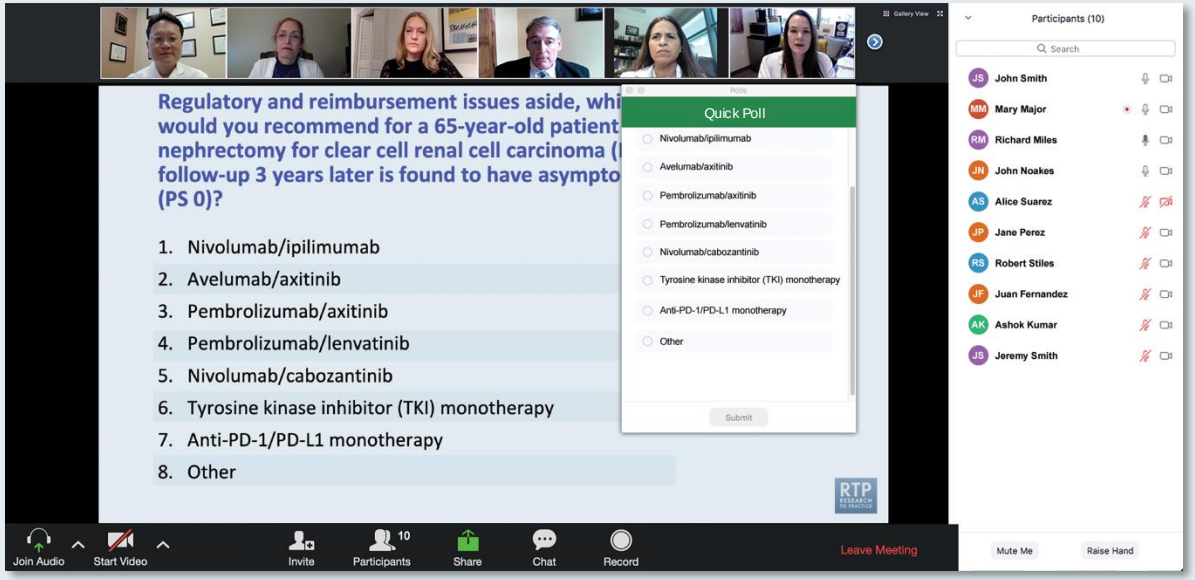
Familiarizing Yourself with the Zoom Interface

Increase chat font size



Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys



ONCOLOGY TODAY

WITH DR NEIL LOVE

Optimizing the Management of Metastatic BRCA-Negative, Triple-Negative Breast Cancer

DR TIFFANY TRAINA

MEMORIAL SLOAN KETTERING CANCER CENTER
AND WEILL CORNELL MEDICAL COLLEGE

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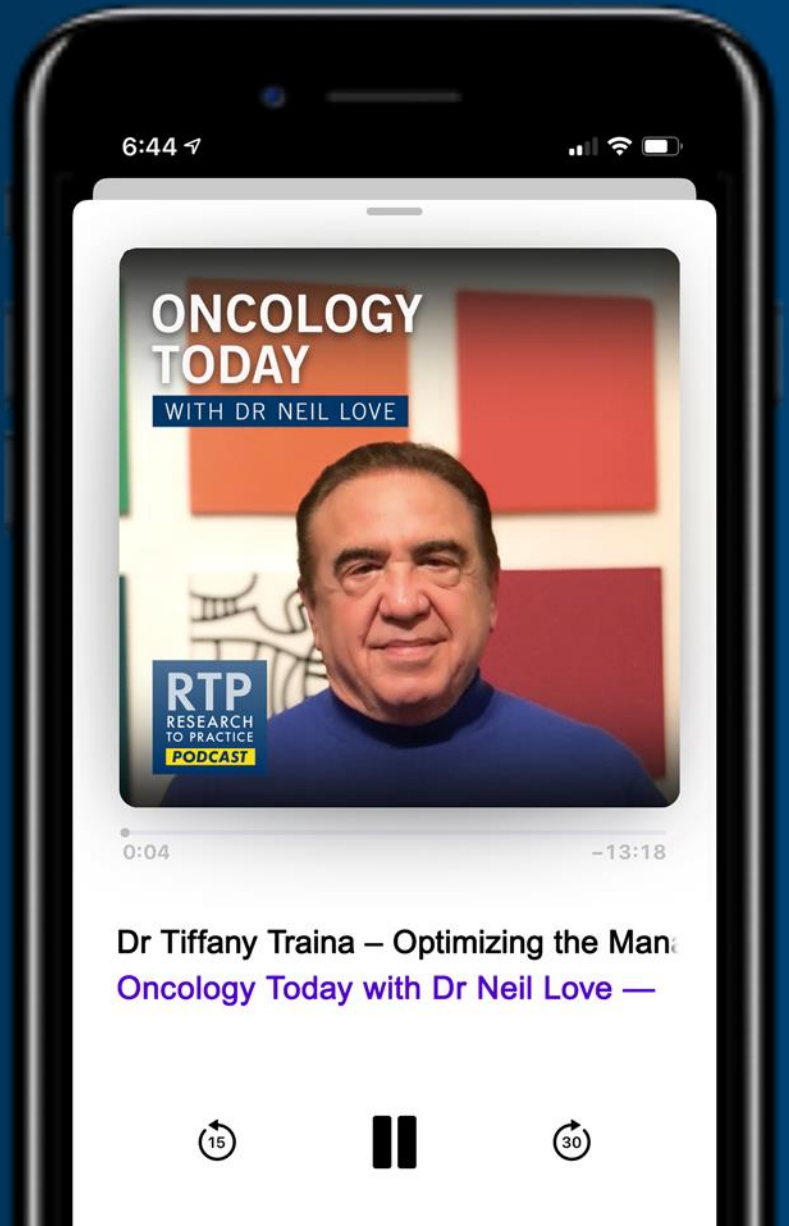

Meet The Professor: Current and Future Use of Nontargeted Therapy for Metastatic Non-Small Cell Lung Cancer — A 2024 World Conference on Lung Cancer Review

A CME/MOC-Accredited Live Webinar

Tuesday, November 19, 2024
5:00 PM – 6:00 PM ET

Faculty

Heather Wakelee, MD, FASCO

Moderator

Neil Love, MD

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RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Hematologic Cancers

A CME Friday Satellite Symposium and Webcast Series
Preceding the 66th ASH Annual Meeting and Exposition

Friday, December 6, 2024

Chronic Myeloid Leukemia
7:30 AM – 9:00 AM PT

Chronic Lymphocytic Leukemia
7:30 AM – 9:30 AM PT

CAR T-Cell Therapy and Bispecific Antibodies in Lymphoma
11:30 AM – 1:30 PM PT

Myelofibrosis
11:30 AM – 1:30 PM PT

Acute Myeloid Leukemia
3:15 PM – 5:15 PM PT

Multiple Myeloma
3:15 PM – 5:15 PM PT

RTP RESEARCH TO PRACTICE

Rounds with the Investigators: Compelling Teaching Cases Focused on the Management of Breast Cancer

A 3-Part CME Hybrid Satellite Symposium Series in Partnership with the 2024 San Antonio Breast Cancer Symposium®

HER2-Low and HER2-Ultralow Breast Cancer

Tuesday, December 10, 2024

7:15 PM – 8:45 PM CT

New Developments in Endocrine Treatment for Breast Cancer

Wednesday, December 11, 2024

7:15 PM – 9:15 PM CT

Management of Metastatic Breast Cancer

Thursday, December 12, 2024

7:00 PM – 9:00 PM CT

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Save The Date

Fourth Annual
National General Medical Oncology Summit

A Multitumor CME/MOC-, NCPD- and ACPE-Accredited Educational Conference Developed in Partnership with Florida Cancer Specialists & Research Institute

Friday to Sunday, February 28 to March 2, 2025

Fontainebleau Hotel, Miami Beach, Florida

Moderated by Neil Love, MD

Thank you for joining us!

Information on how to obtain CME, ABIM MOC and ABS credit will be provided at the conclusion of the activity in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

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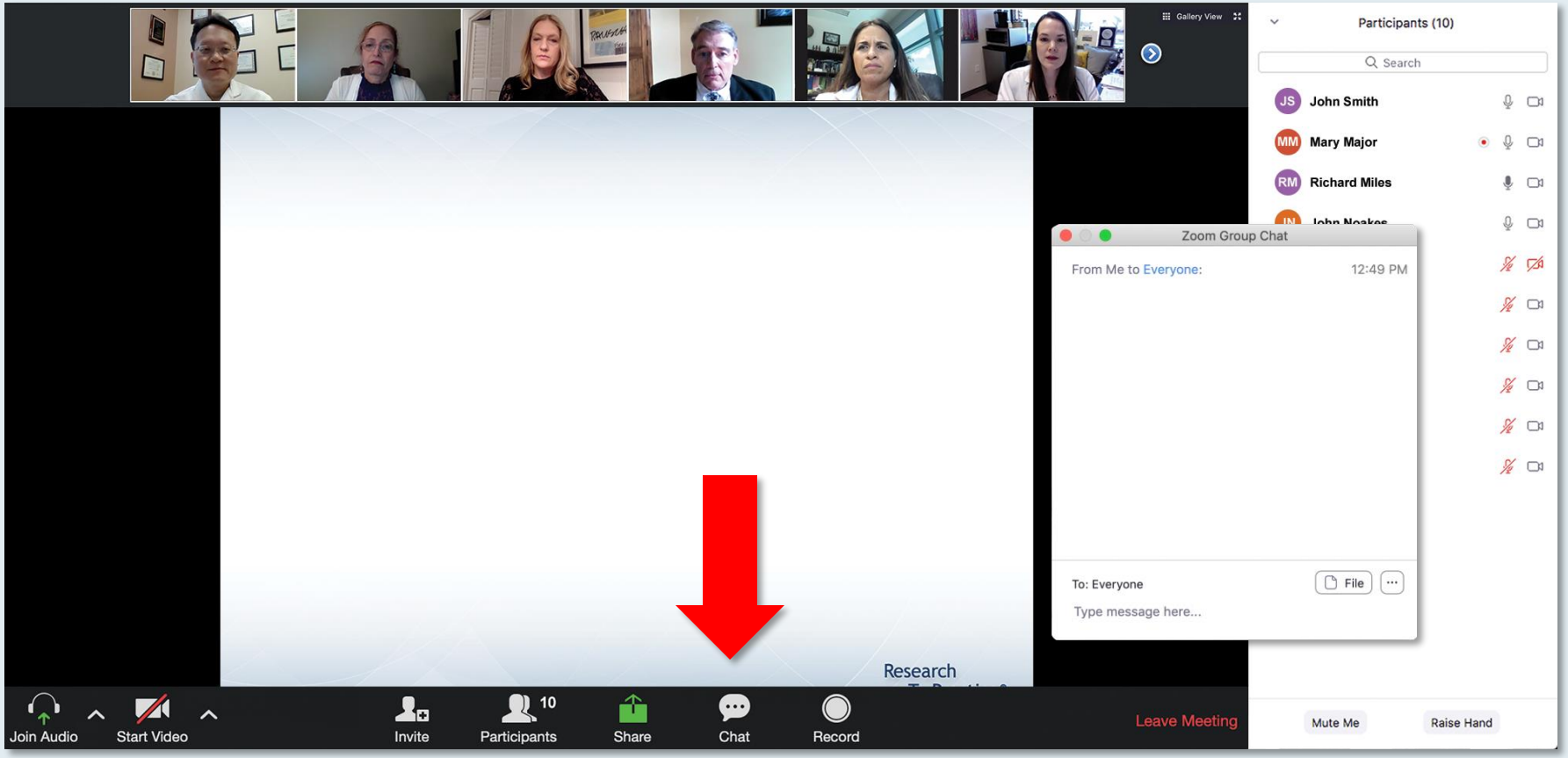

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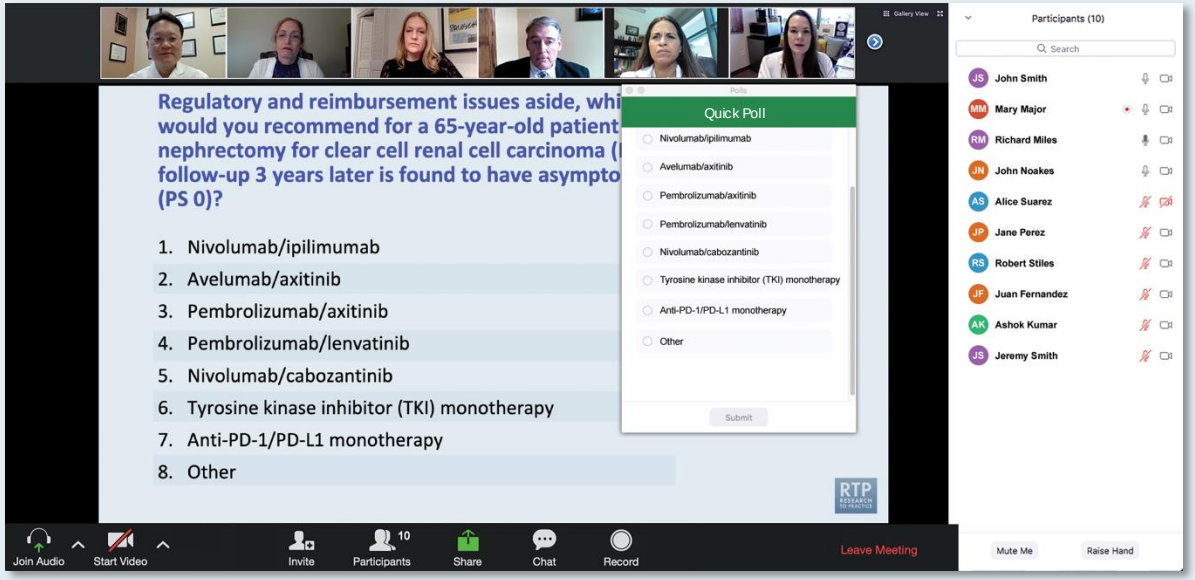

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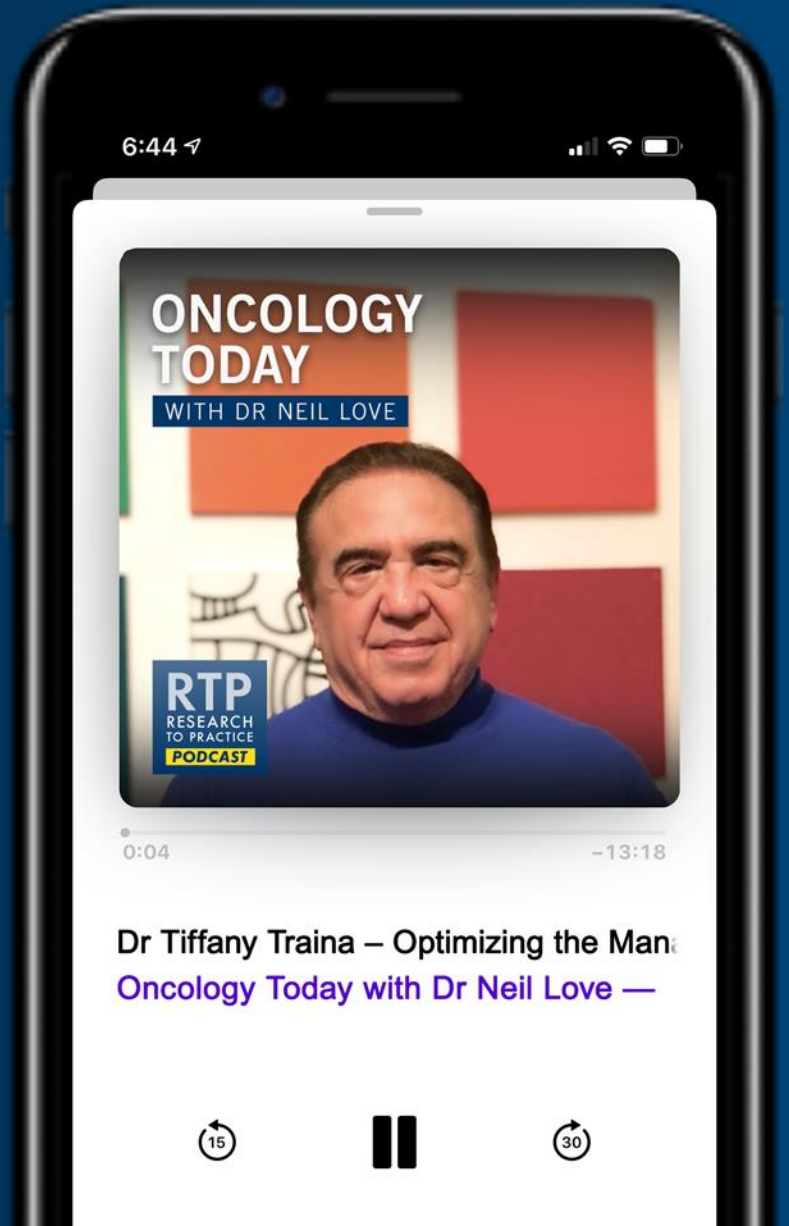

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Cases from the Community: Integrating New Research Findings into Practice

A Multitumor Symposium in Partnership with the American Oncology Network

CME/MOC, NCPD and ACPE Accredited

Saturday, November 16, 2024
9:30 AM – 4:00 PM CT

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Contributing General Medical Oncologists

Ralph V Boccia, MD
Center for Cancer and
Blood Disorders
Bethesda, Maryland

Brian P Mulherin, MD
Hematology Oncology
of Indiana
Indianapolis, Indiana

Jeanna L Knoble, MD
The Mark H Zangmeister
Cancer Center
Columbus, Ohio

Taral Patel, MD
The Mark H Zangmeister
Cancer Center
Columbus, Ohio

Zanetta S Lamar, MD
Florida Oncology and
Hematology
American Oncology Partners
Naples, Florida

Sean Warsch, MD
Messino Cancer Centers
Asheville, North Carolina

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Contributing General Medical Oncologists

Shaachi Gupta, MD, MPH
Florida Cancer Specialists & Research Institute
West Palm Beach, Florida

Maen Hussein, MD
Florida Cancer Specialists & Research Institute
The Villages, Florida

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TO PRACTICE

Agenda

Introduction Metastatic Triple-Negative Breast Cancer (mTNBC) – The Patient Perspective

Module 1 Selection and sequencing of antibody-drug conjugates

Module 2 Dosing and tolerability of sacituzumab govitecan; use of anthracyclines

Module 3 Case Presentation: 63-year-old woman with relapsed TNBC (HER2 2+) who experiences disease progression on T-DXd (Grade 2 ILD) and receives sacituzumab govitecan

Module 4 Discussing palliative and end-of-life care

Module 5 PARP inhibitors in somatic versus germline mutant TNBC; cytopenias with PARP inhibitors

Module 6 The "art of oncology" – building trust with patients and family members

Module 7 Case Presentation: 66-year-old woman with recurrent TNBC with extensive chest wall involvement

Module 8 Case Presentation: 45-year-old man with multiregimen-refractory AR-positive TNBC with an ERBB2 exon 20 insertion mutation

RTP RESEARCH TO PRACTICE

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Oncology Q&A: Addressing Common Questions Posed by Patients with Metastatic Triple-Negative Breast Cancer

A Live Webinar for Patients, Developed in Partnership with the Triple Negative Breast Cancer Foundation

Wednesday, November 13, 2024
6:00 PM – 7:00 PM ET

Faculty

Lisa A Carey, MD, ScM, FASCO
Rita Nanda, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

2022 ASCO ANNUAL MEETING

DESTINY-Breast04

Trastuzumab deruxtecan (T-DXd) vs treatment of physician's choice in patients with HER2-low unresectable and/or metastatic breast cancer: Results of DESTINY-Breast04, a randomized, phase 3 study

Shanu Modi Memorial Sloan Kettering Cancer Center, Memorial Hospital, New York, NY, USA

June 5, 2022

Additional authors: William Jacot, Toshinari Yamashita, Joo Hyuk Sohn, Maria Vidal, Eriko Tokunaga, Junji Tsurutani, Naoto Ueno, Yee Soo Chae, Keun Seok Lee, Naoki Niikura, Yeon Hee Park, Xiaojia Wang, Binghe Xu, Dhiraj Gambhire, Lotus Yung, Gerold Meinhardt, Yibin Wang, Nadia Harbeck, David Cameron

On behalf of the DESTINY-Breast04 investigators

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JULY 7, 2022 VOL. 387 NO. 1

Trastuzumab Deruxtecan in Previously Treated HER2-Low Advanced Breast Cancer

S. Modi, W. Jacot, T. Yamashita, J. Sohn, M. Vidal, E. Tokunaga, J. Tsurutani, N.T. Ueno, A. Prat, Y.S. Chae, K.S. Lee, N. Niikura, Y.H. Park, B. Xu, X. Wang, M. Gil-Gil, W. Li, J.-Y. Pierga, S.-A. Im, H.C.F. Moore, H.S. Rugo, R. Yerushalmi, F. Zagouri, A. Gombos, S.-B. Kim, Q. Liu, T. Luo, C. Saura, P. Schmid, T. Sun, D. Gambhire, L. Yung, Y. Wang, J. Singh, P. Vitazka, G. Meinhardt, N. Harbeck, and D.A. Cameron, for the DESTINY-Breast04 Trial Investigators*

Beyond the Guidelines: Clinical Investigator Perspectives on the Management of Breast Cancer

A CME Hybrid Symposium Held in Conjunction with the 2022 ASCO Annual Meeting

Monday, June 6, 2022
7:00 PM – 9:30 PM CT (8:00 PM – 10:30 PM ET)

Faculty

Javier Cortés, MD, PhD
Matthew P Goetz, MD
Erika Hamilton, MD
Ian E Krop, MD, PhD
Hope S Rugo, MD
Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

2024 ASCO ANNUAL MEETING

DESTINY BREAST06

Trastuzumab deruxtecan vs physician's choice of chemotherapy in patients with hormone receptor–positive, human epidermal growth factor receptor 2 (HER2)–low or HER2-ultralow metastatic breast cancer with prior endocrine therapy: primary results from DESTINY-Breast06

Giuseppe Curigliano
European Institute of Oncology, IRCCS, Milan, Italy;
Department of Oncology and Hematology-Oncology, University of Milan, Italy

Sunday, June 2, 2024

Additional authors: Xichun Hu, Rebecca Dent, Kan Yonemori, Carlos H Barrios, Joyce A O'Shaughnessy, Hans Wildiers, Qingyuan Zhang, Seock-Ah Im, Cristina Saura, Laura Biganzoli, Joohyuk Sohn, Christelle Lévy, William Jacot, Natasha Begbie, Jun Ke, Gargi Patel, Aditya Bardia

On behalf of the DESTINY-Breast06 investigators

2024 ASCO ANNUAL MEETING #ASCO24 PRESENTED BY: Giuseppe Curigliano, MD, PhD

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY KNOWLEDGE CONQUERS CANCER

The NEW ENGLAND JOURNAL of MEDICINE

Published online September 15, 2024.

ORIGINAL ARTICLE

Trastuzumab Deruxtecan after Endocrine Therapy in Metastatic Breast Cancer

A. Bardia, X. Hu, R. Dent, K. Yonemori, C.H. Barrios, J.A. O'Shaughnessy, H. Wildiers, J.-Y. Pierga, Q. Zhang, C. Saura, L. Biganzoli, J. Sohn, S.-A. Im, C. Lévy, W. Jacot, N. Begbie, J. Ke, G. Patel, and G. Curigliano, for the DESTINY-Breast06 Trial Investigators*

What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Metastatic Breast Cancer

A CME Hybrid Symposium Held in Conjunction with the 2024 ASCO Annual Meeting

Monday, June 3, 2024

7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Aditya Bardia, MD, MPH

Harold J Burstein, MD, PhD

Professor Giuseppe Curigliano, MD, PhD

Sara A Hurvitz, MD, FACP

Joyce O'Shaughnessy, MD

Moderator

Hope S Rugo, MD

RTP RESEARCH TO PRACTICE

FDA Grants Accelerated Approval to Trastuzumab Deruxtecan for Unresectable or Metastatic HER2-Positive Solid Tumors

Press Release: April 5, 2024

"The Food and Drug Administration granted accelerated approval to fam-trastuzumab deruxtecan-nxki for adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.

Efficacy was evaluated in 192 adult patients with previously treated unresectable or metastatic HER2-positive (IHC 3+) solid tumors who were enrolled in one of three multicenter trials: DESTINY-PanTumor02 (NCT04482309), DESTINY-Lung01 (NCT03505710), and DESTINY-CRC02 (NCT04744831). All three trials excluded patients with a history of interstitial lung disease (ILD)/pneumonitis requiring treatment with steroids or ILD/pneumonitis at screening and clinically significant cardiac disease. Patients were also excluded for active brain metastases or ECOG performance status >1. Treatment was administered until disease progression, death, withdrawal of consent, or unacceptable toxicity.

The recommended fam-trastuzumab deruxtecan-nxki dosage for this indication is 5.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.

This tumor agnostic indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-her2

RTP RESEARCH TO PRACTICE

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RTP RESEARCH TO PRACTICE

Selection and sequencing of antibody-drug conjugates

Dr Shaachi Gupta (West Palm Beach, Florida)

RTP
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RTP RESEARCH TO PRACTICE

Dosing and tolerability of sacituzumab govitecan; use of anthracyclines

Dr Maen Hussein (The Villages, Florida)

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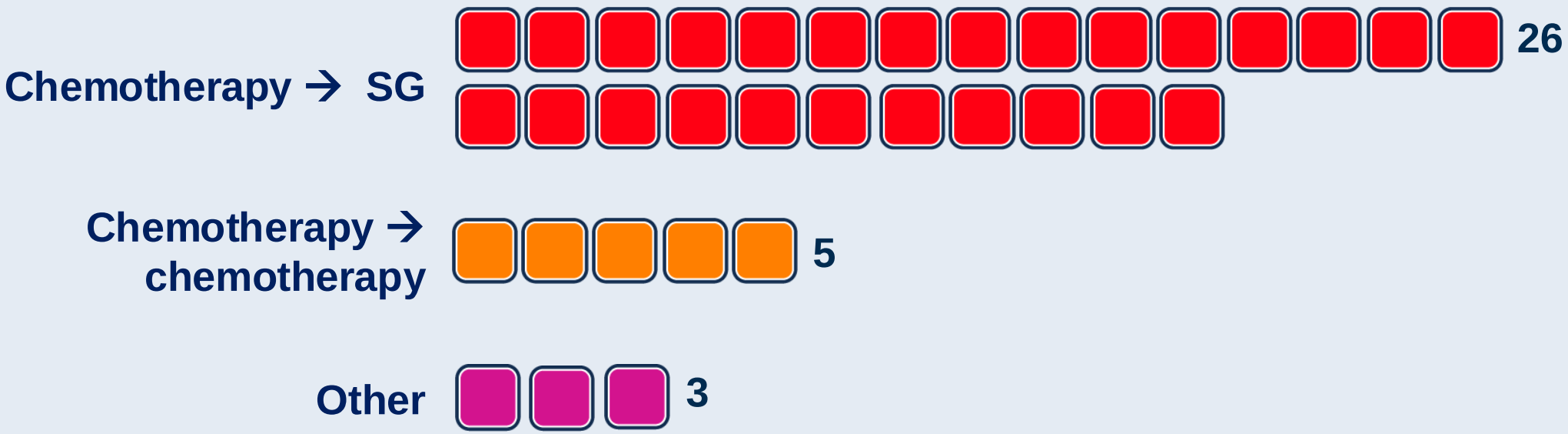
RTP RESEARCH TO PRACTICE

Case Presentation: 63-year-old woman with relapsed TNBC (HER2 2+) who experiences disease progression on T-DXd (Grade 2 ILD) and receives sacituzumab govitecan

Dr Shaachi Gupta (West Palm Beach, Florida)

RTP RESEARCH TO PRACTICE

65-year-old patient with de novo metastatic ER-negative, BRCA-WT BC HER2-negative (IHC 0) PD-L1 combined positive score (CPS) 0



SG = sacituzumab govitecan

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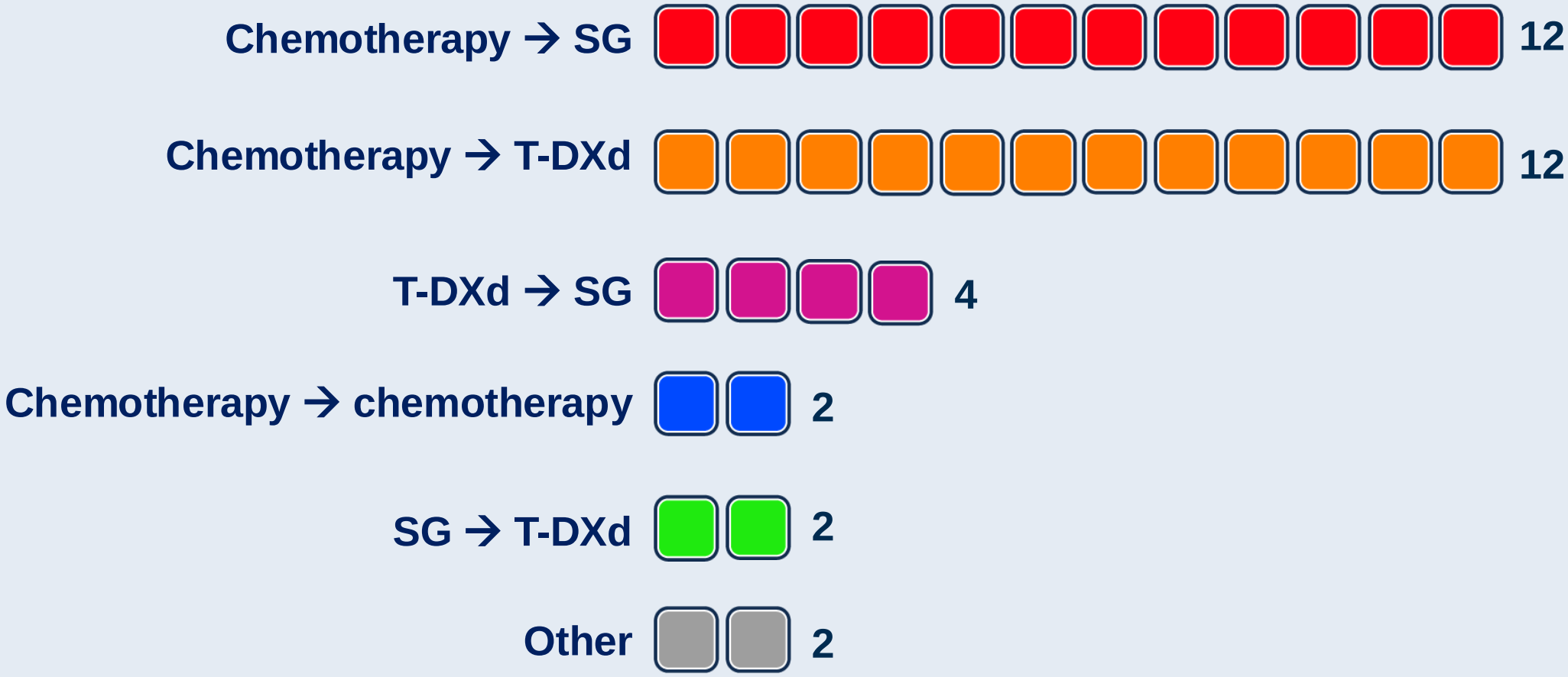
RTP RESEARCH TO PRACTICE

65-year-old patient with de novo metastatic ER-negative, BRCA wild-type (WT) BC

HER2 ultralow (IHC >0 but <1+)

PD-L1 combined positive score (CPS) 0



SG = sacituzumab govitecan; T-DXd = trastuzumab deruxtecan

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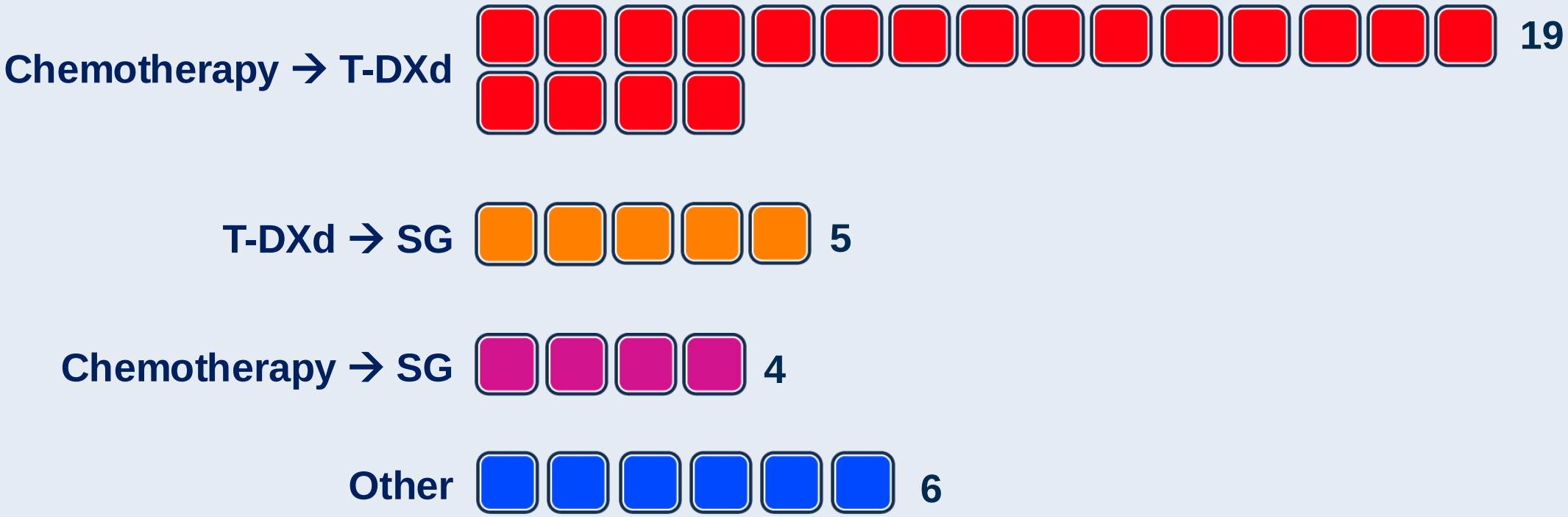
65-year-old patient with de novo metastatic ER-negative, BRCA-WT BC HER2 low (IHC 1+ or IHC 2+/ISH-negative) PD-L1 CPS 0?



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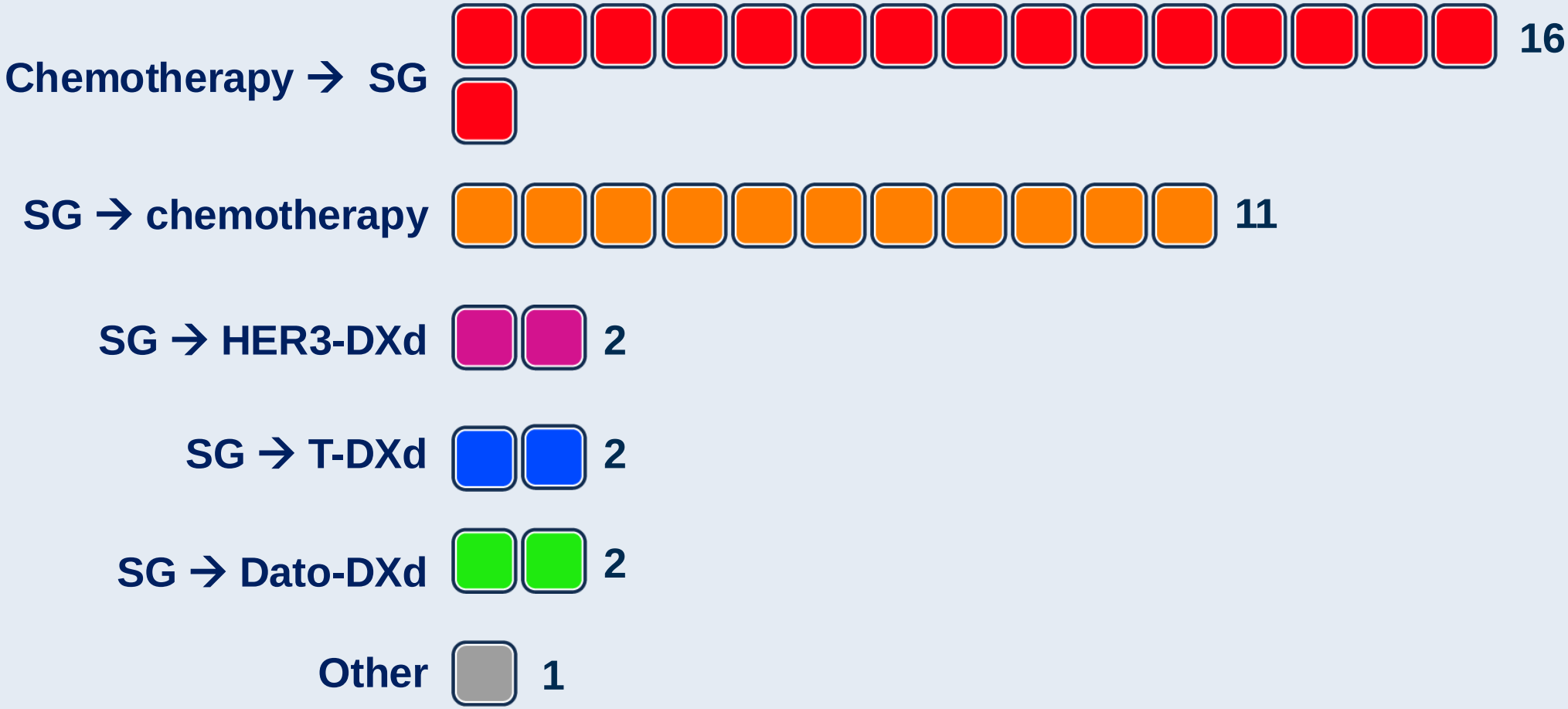
65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 4 months after completing (neo)adjuvant IO

HER2-negative (IHC 0)
PD-L1 CPS 0



IO = immunotherapy; HER3-DXd = patritumab deruxtecan; Dato-DXd = datopotamab deruxtecan

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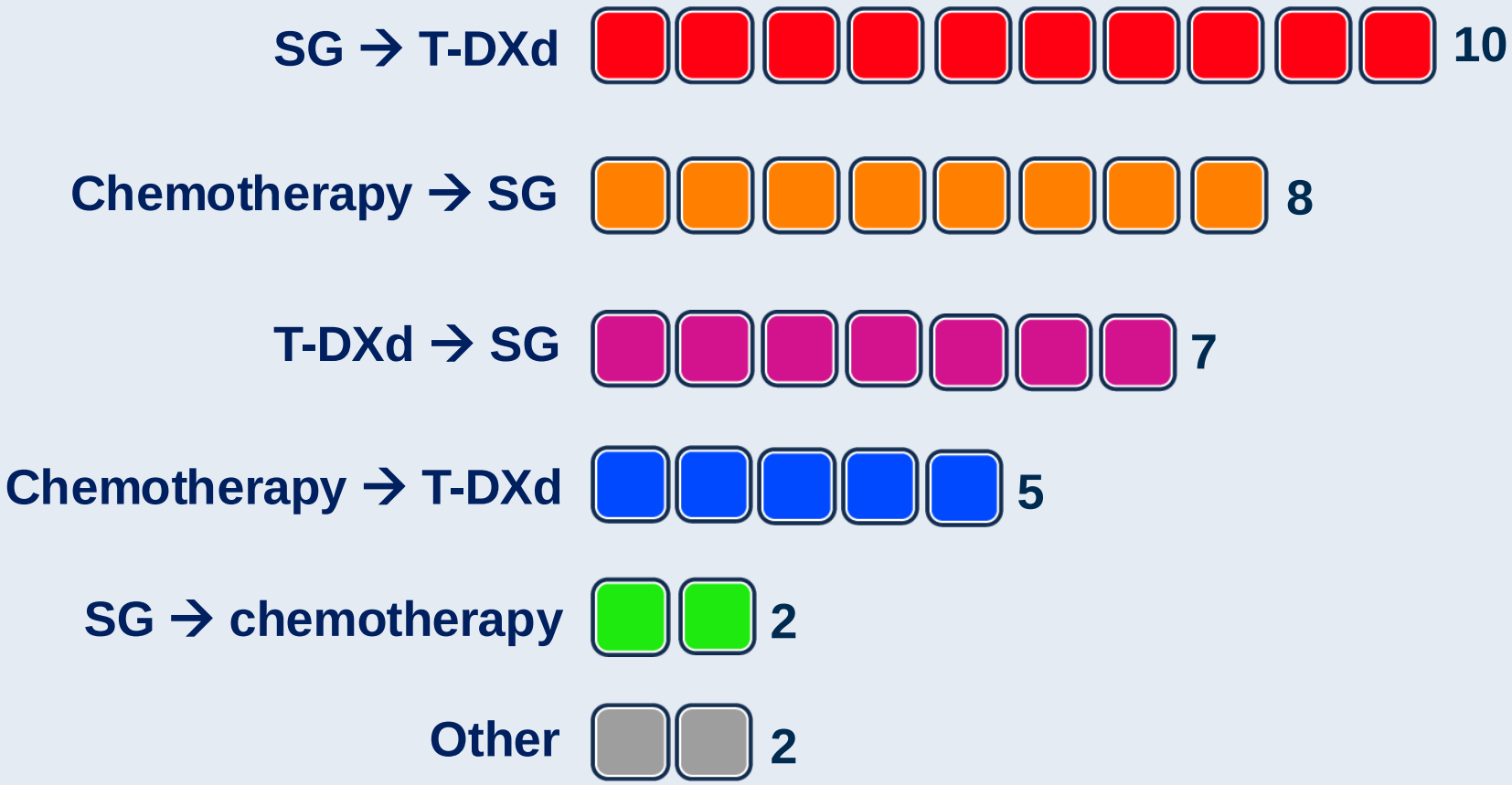
RTP RESEARCH TO PRACTICE

65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 4 months after completing (neo)adjuvant IO

HER2 ultralow (IHC >0 but <1+)

PD-L1 CPS 0



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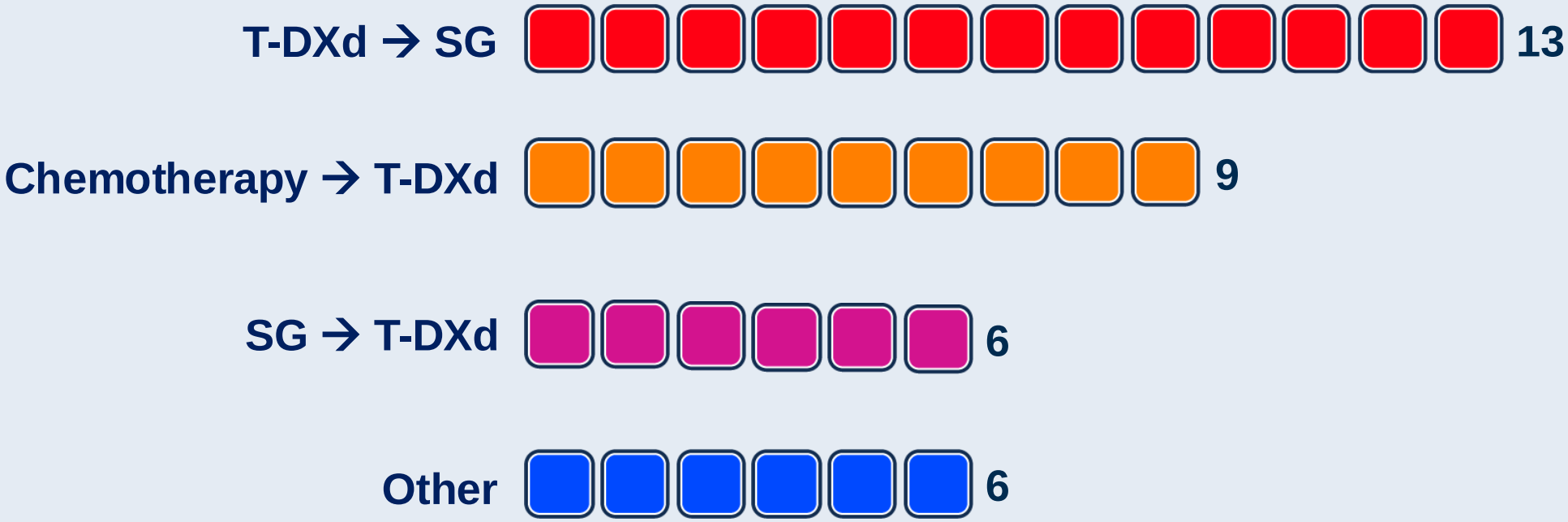

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Patients who received both SG and T-DXd

	SG → T-DXd (n = 10)		T-DXd → SG (n = 8)	
	TTNT w/ SG (months)	TTNT w/ T-DXd (months)	TTNT w/ T-DXd (months)	TTNT w/ SG (months)
	9	3*	14	18*
	15	2*	10	6
	2	4*	5	9
	1	3	2	9
	10	8	7	4
	10	9	6	8
	3	4	9	3*
	3	2	10	10*
	6	3*	—	—
	6	5	—	—
Median	6	4.5	8	8

N = 125

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* Current therapy
TTNT = time to next treatment

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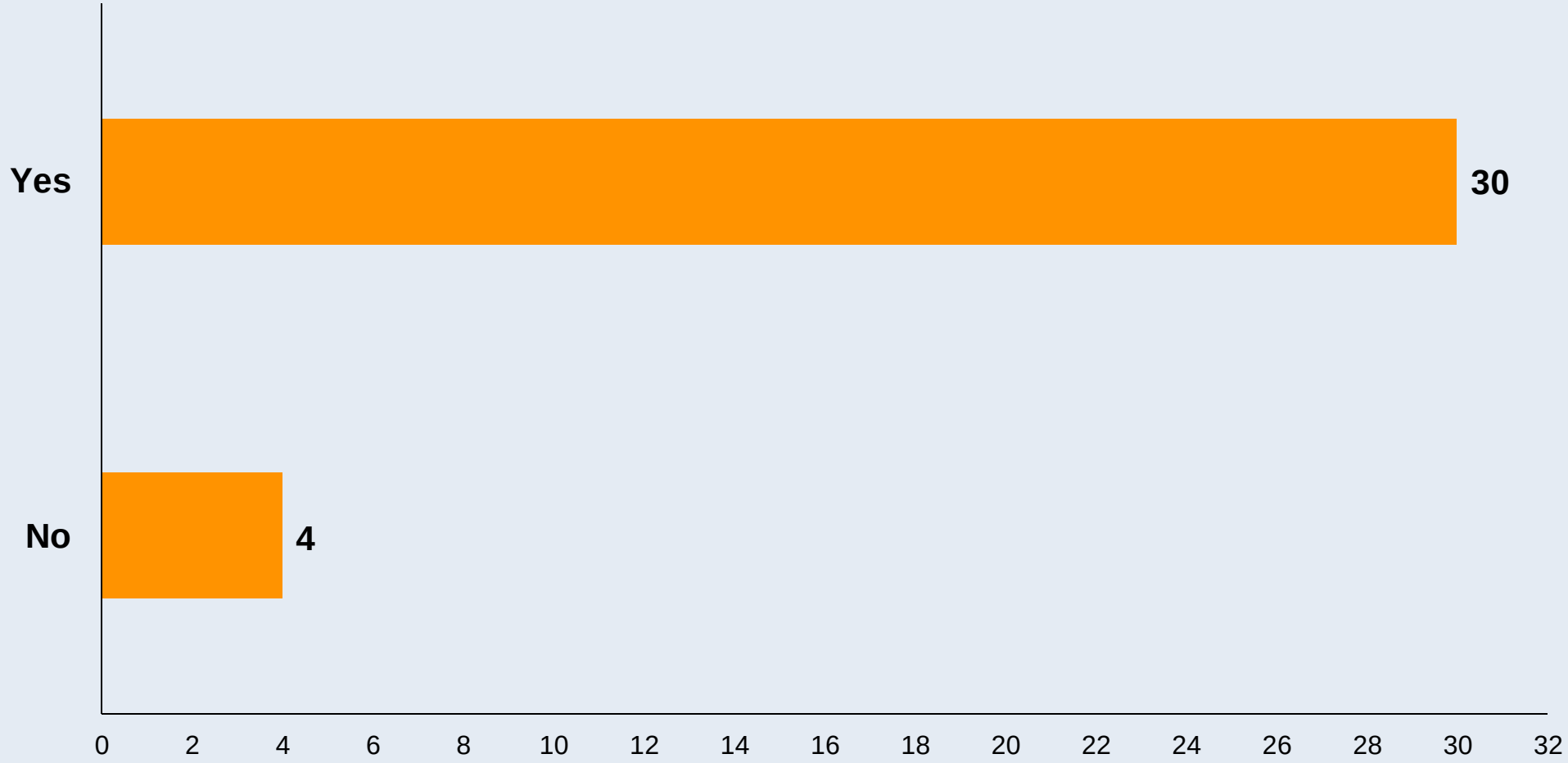
Regulatory and reimbursement issues aside, would you offer T-DXd to a patient with ER-negative, HER2-ultralow (IHC >0 but <1+) metastatic breast cancer (mBC)?



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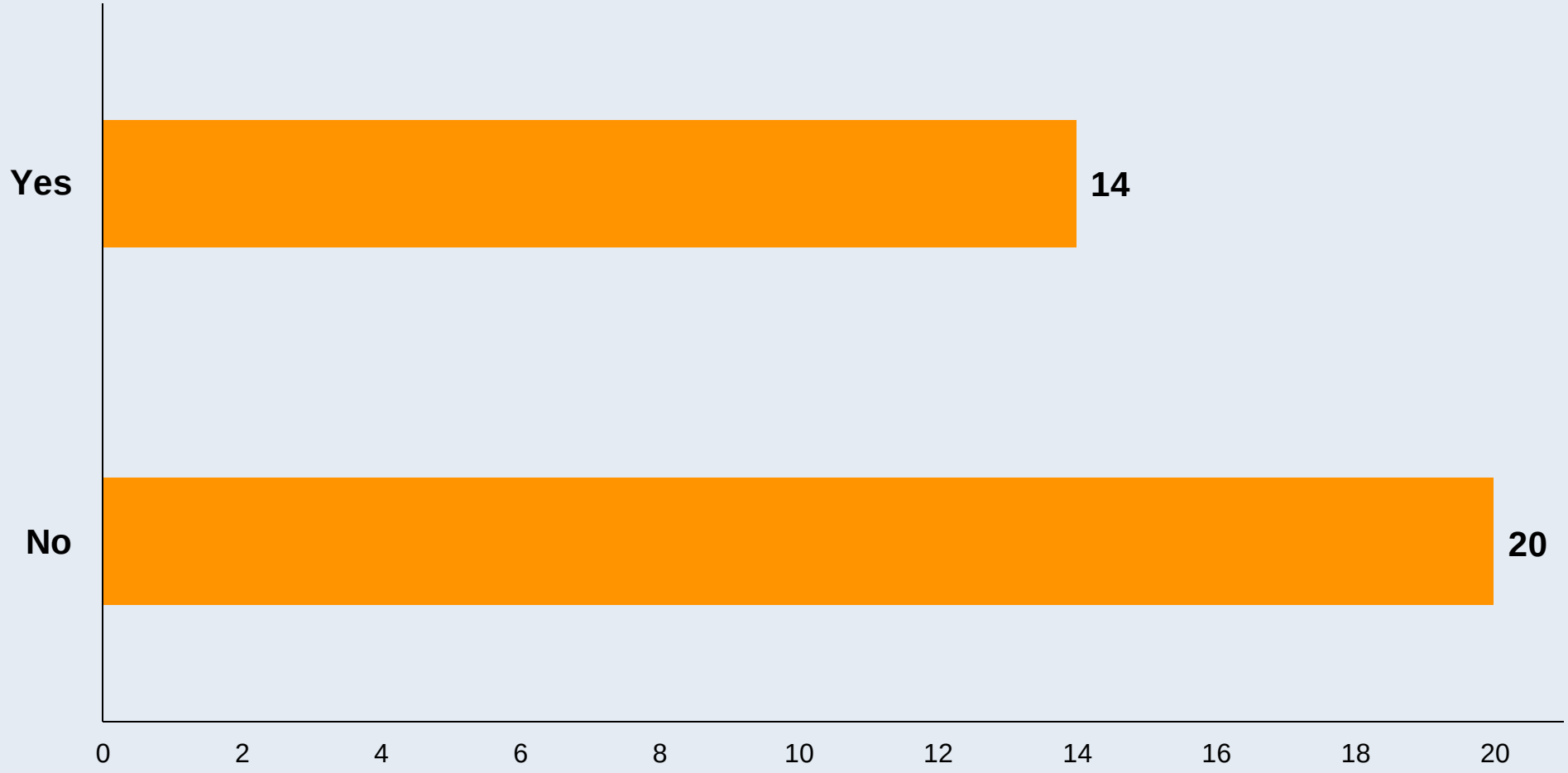
Regulatory and reimbursement issues aside, would you offer T-DXd to a patient with HER2 IHC 0 mBC with a HER2 mutation?



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	Median
Number of patients with mTNBC to whom you have administered sacituzumab govitecan either on or off protocol	5
Likelihood that a patient receiving sacituzumab govitecan will need to have therapy held because of tolerability issues	30%
Likelihood that a patient receiving sacituzumab govitecan will need to have therapy discontinued because of tolerability issues	10%

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RTP RESEARCH TO PRACTICE

For your patients who are receiving sacituzumab govitecan, do you routinely administer G-CSF prophylaxis or wait until neutropenia develops to initiate treatment?

Prophylaxis	**32%**	**11**
Initiate when neutropenia develops	**56%**	**19**
Other	**12%**	**4**

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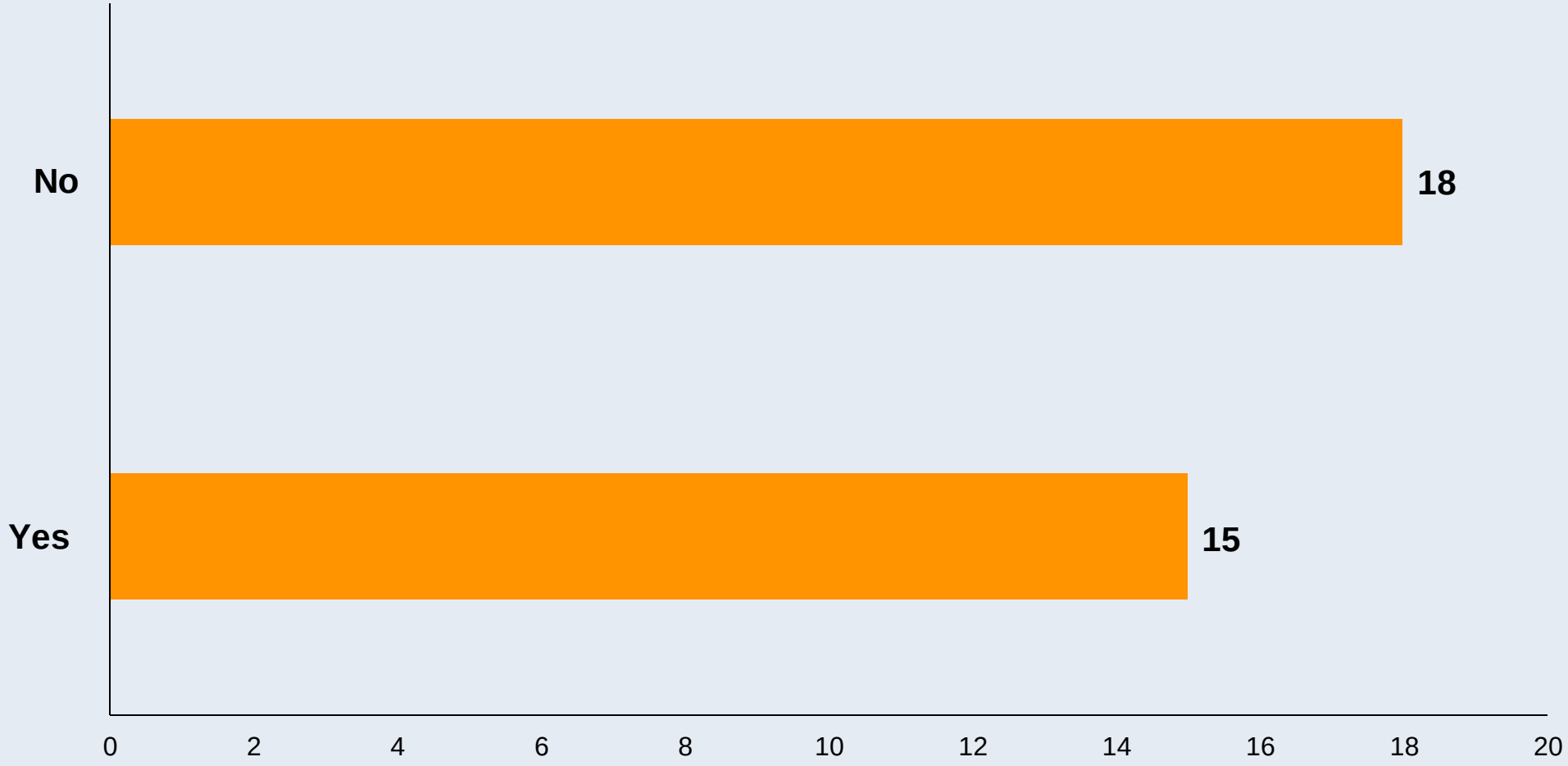
Do you generally recommend any form of prophylaxis to prevent GI toxicities in patients about to start therapy with sacituzumab govitecan?



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RTP RESEARCH TO PRACTICE

	Median
Number of patients with mTNBC (HER2 low or ultralow) to whom you have administered T-DXd either on or off protocol?	7

What grade of ILD would lead you to permanently discontinue treatment with T-DXd?	
Grade 1	0
Grade 2	26
Grade 3	8
Grade 4	0

ILD = interstitial lung disease

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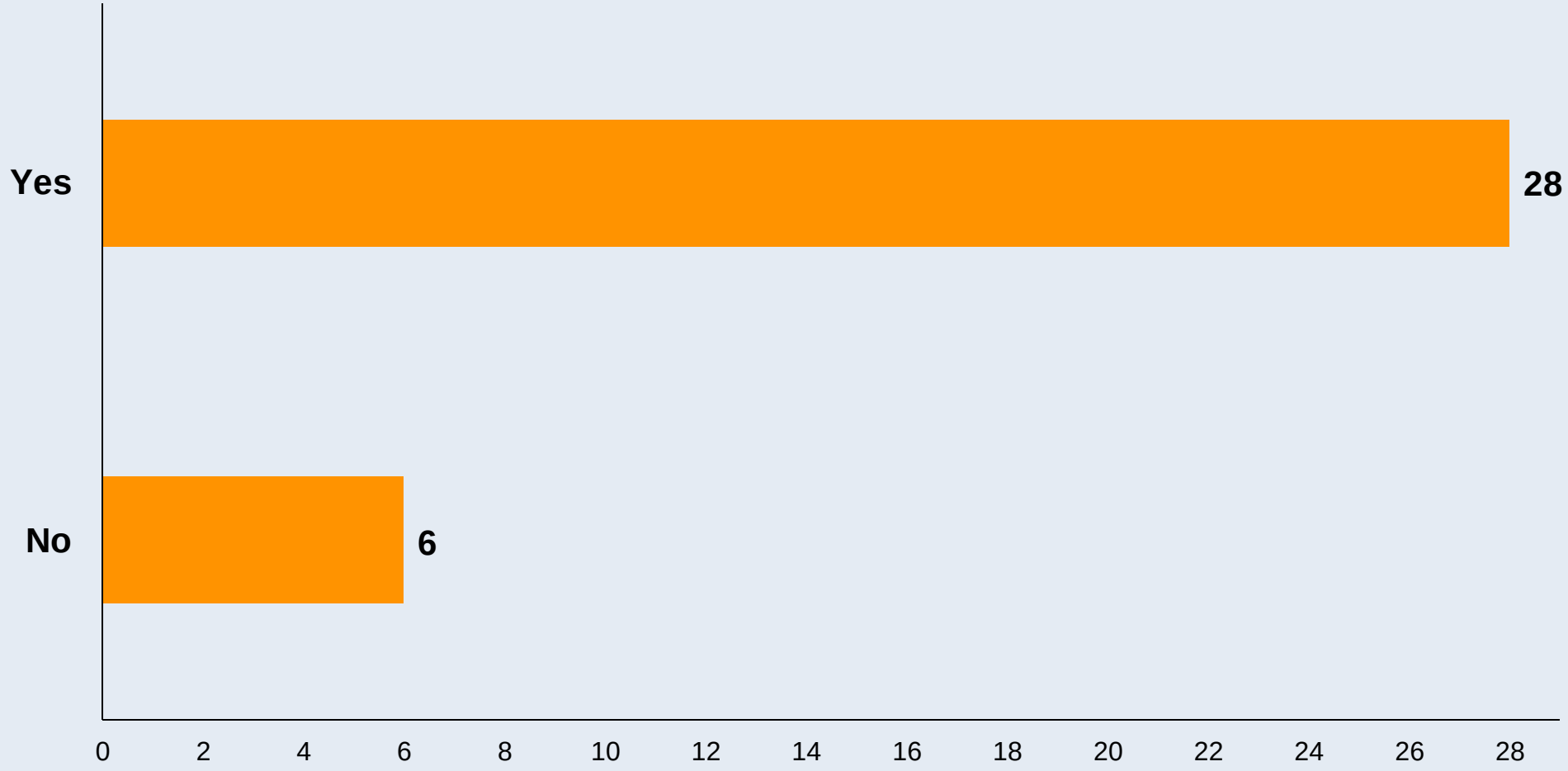
Do you use chest imaging to monitor a patient receiving T-DXd who otherwise does not require chest imaging?



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RTP RESEARCH TO PRACTICE

Discussing palliative and end-of-life care

Dr Maen Hussein (The Villages, Florida)

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RTP RESEARCH TO PRACTICE

PARP inhibitors in somatic versus germline mutant TNBC; cytopenias with PARP inhibitors

Dr Shaachi Gupta (West Palm Beach, Florida)

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RTP RESEARCH TO PRACTICE

The “art of oncology” – building trust with patients and their family members

Dr Maen Hussein (The Villages, Florida)

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RTP RESEARCH TO PRACTICE

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RTP RESEARCH TO PRACTICE

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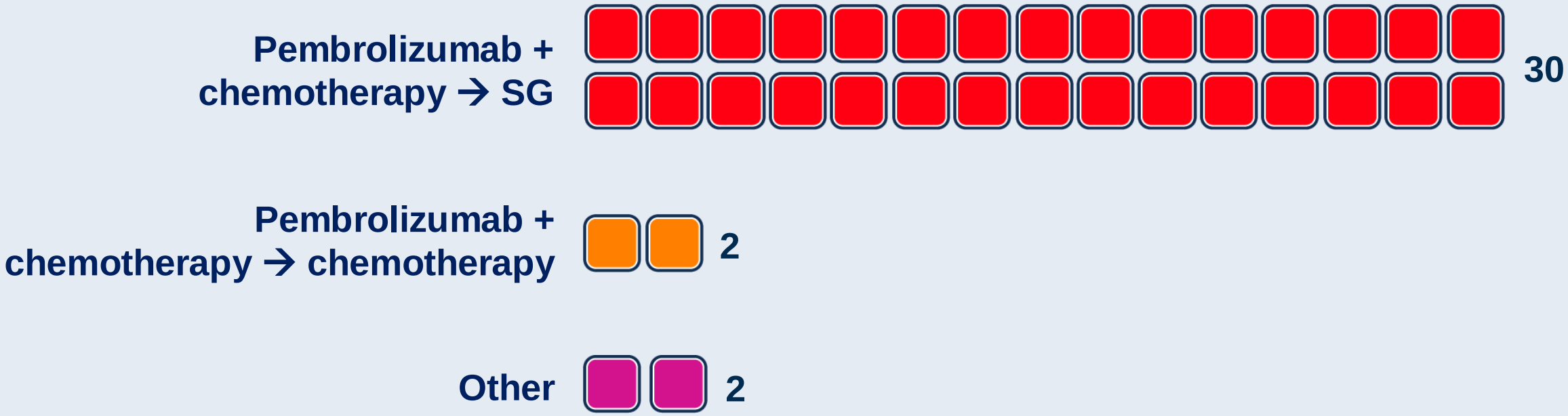
Dr Shaachi Gupta (West Palm Beach, Florida)

RTP RESEARCH TO PRACTICE

Appendix

65-year-old patient with de novo metastatic ER-negative, BRCA-WT BC
HER2-negative (IHC 0)
PD-L1 CPS 50



SG = sacituzumab govitecan

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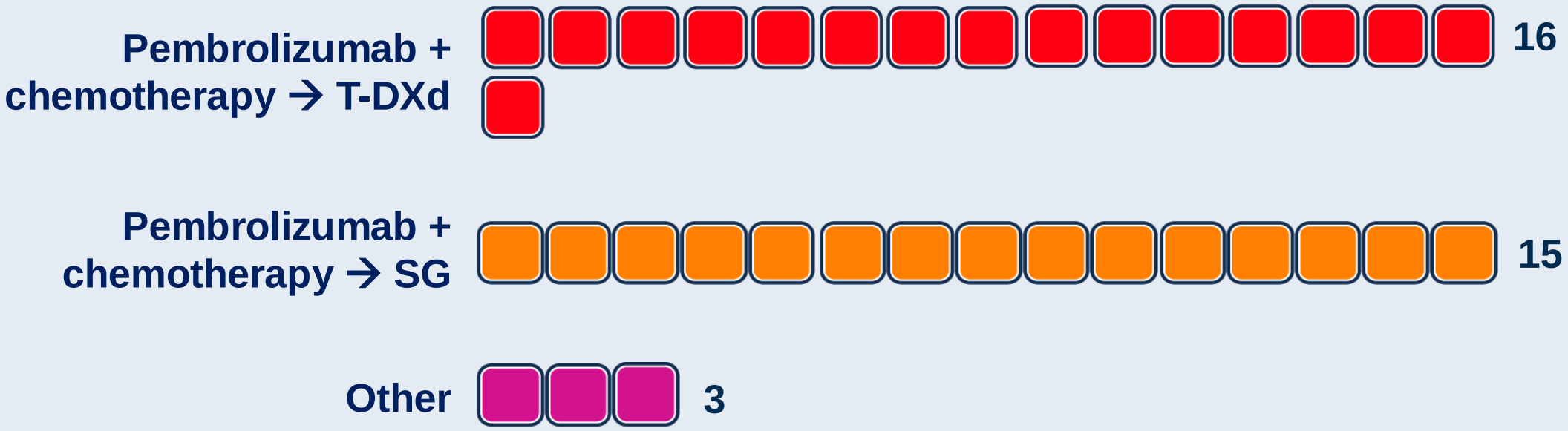
RTP RESEARCH TO PRACTICE

65-year-old patient with de novo metastatic ER-negative, BRCA-WT BC
HER2 ultralow (IHC >0 but <1+)
PD-L1 CPS 50



T-DXd = trastuzumab deruxtecan

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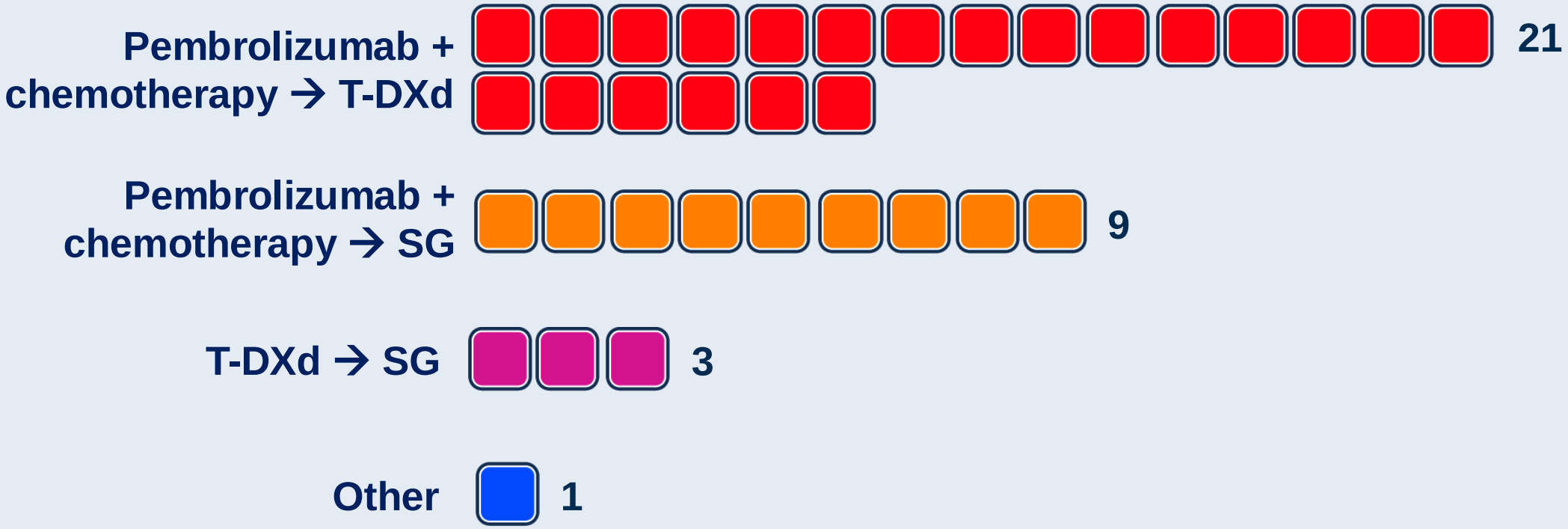
65-year-old patient with de novo metastatic ER-negative, BRCA-WT BC
HER2 low (IHC 1+ or IHC 2+/ISH-negative)
PD-L1 CPS 50



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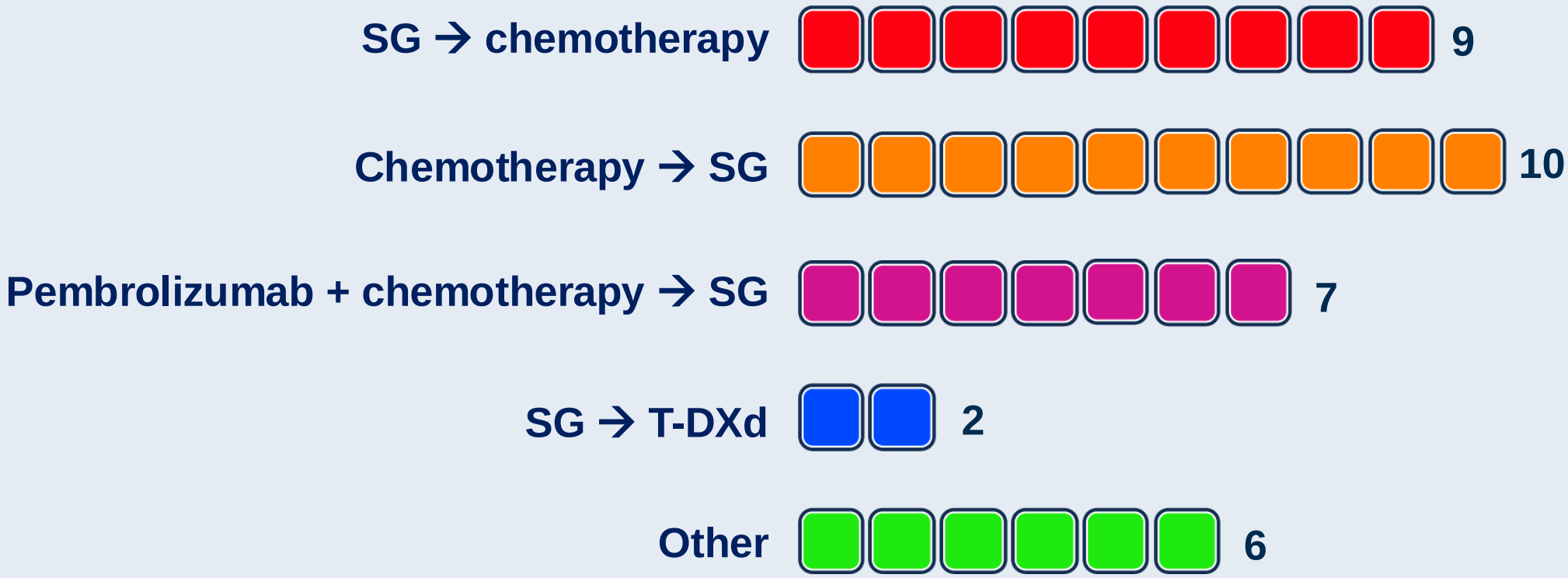
RTP RESEARCH TO PRACTICE

65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 4 months after completing (neo)adjuvant IO

HER2-negative (IHC 0)

PD-L1 CPS 50



IO = immunotherapy

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RTP RESEARCH TO PRACTICE

65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 4 months after completing (neo)adjuvant IO

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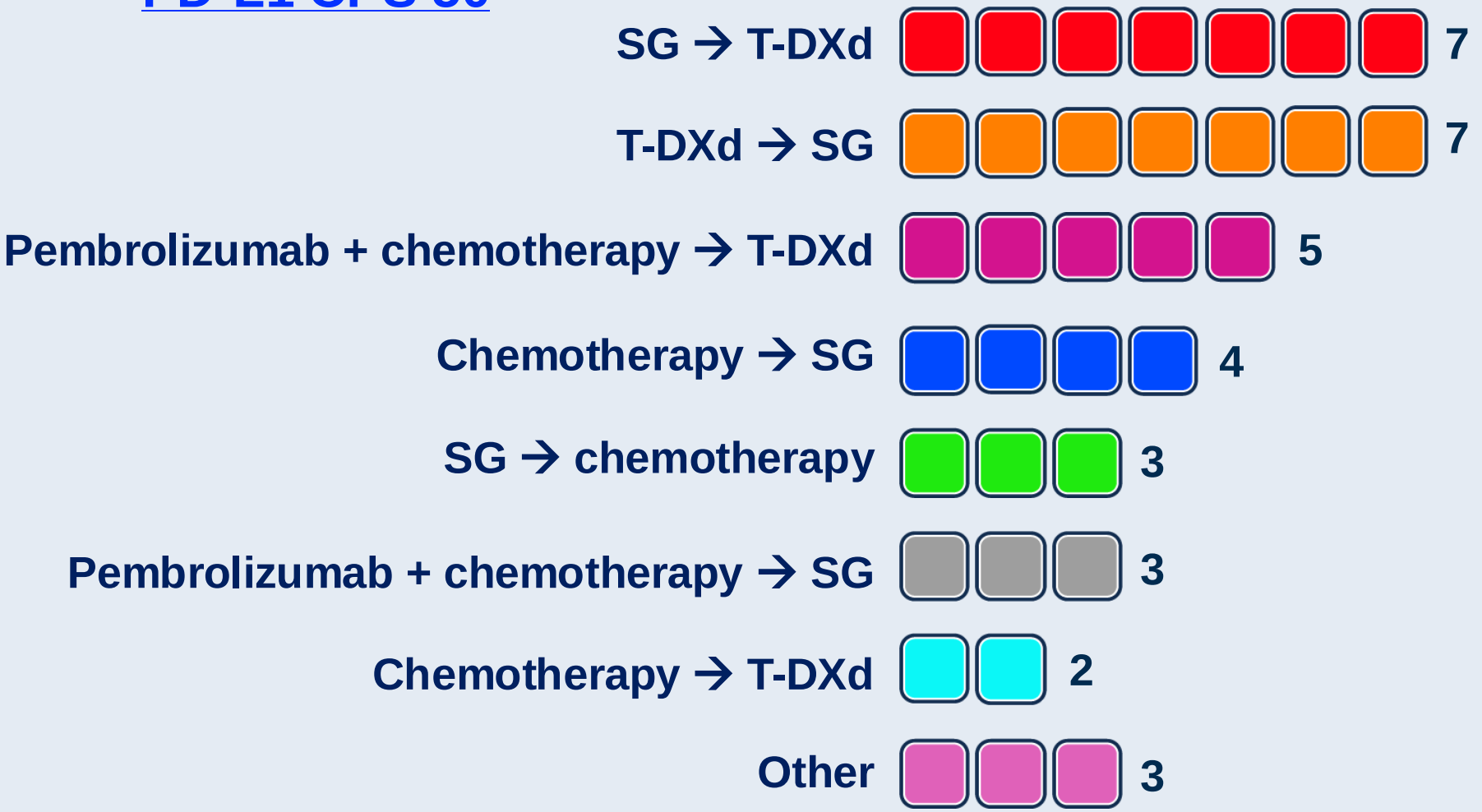
PD-L1 CPS 50



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PD-L1 CPS 50

HER3-DXd = patritumab deruxtecan

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RTP RESEARCH TO PRACTICE

65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 7 months after completing (neo)adjuvant IO

HER2-negative (IHC 0)
PD-L1 CPS 0

Dato-DXd = datopotamab deruxtecan

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RTP RESEARCH TO PRACTICE

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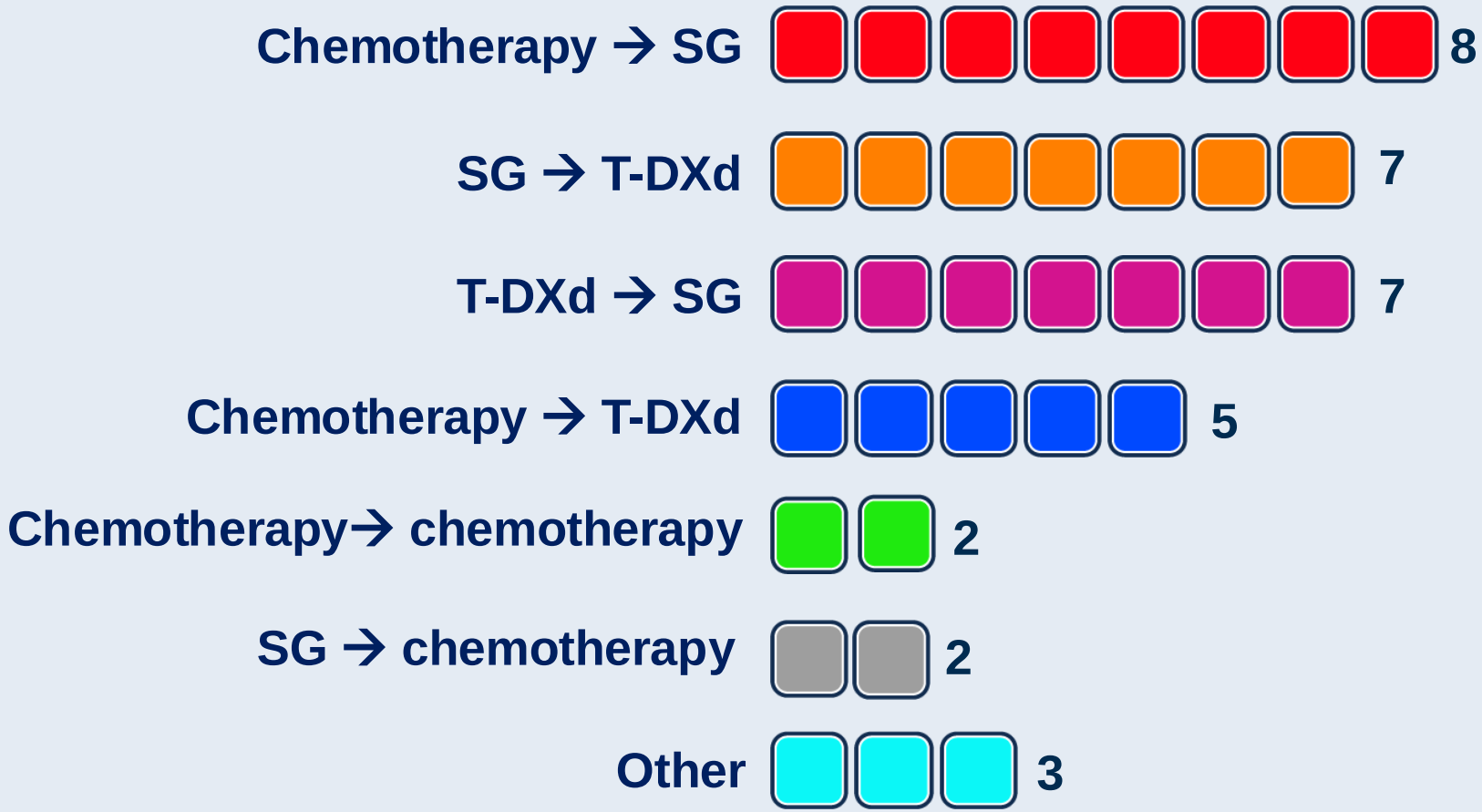

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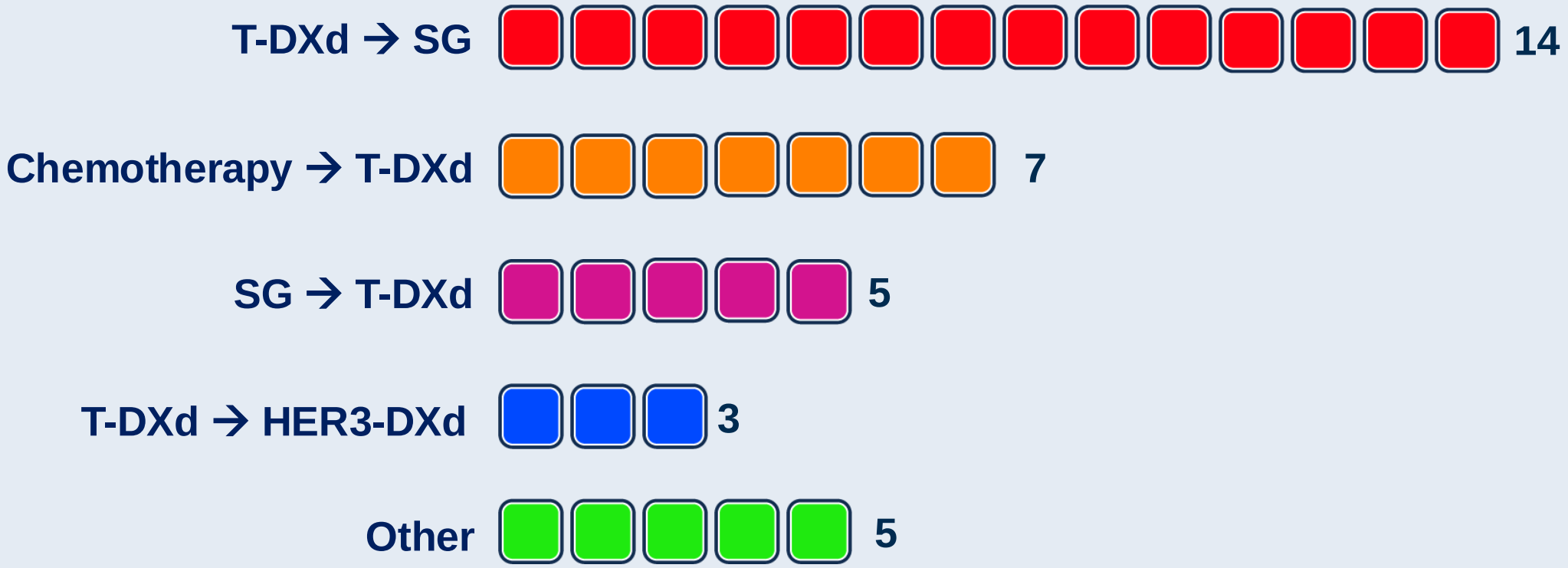

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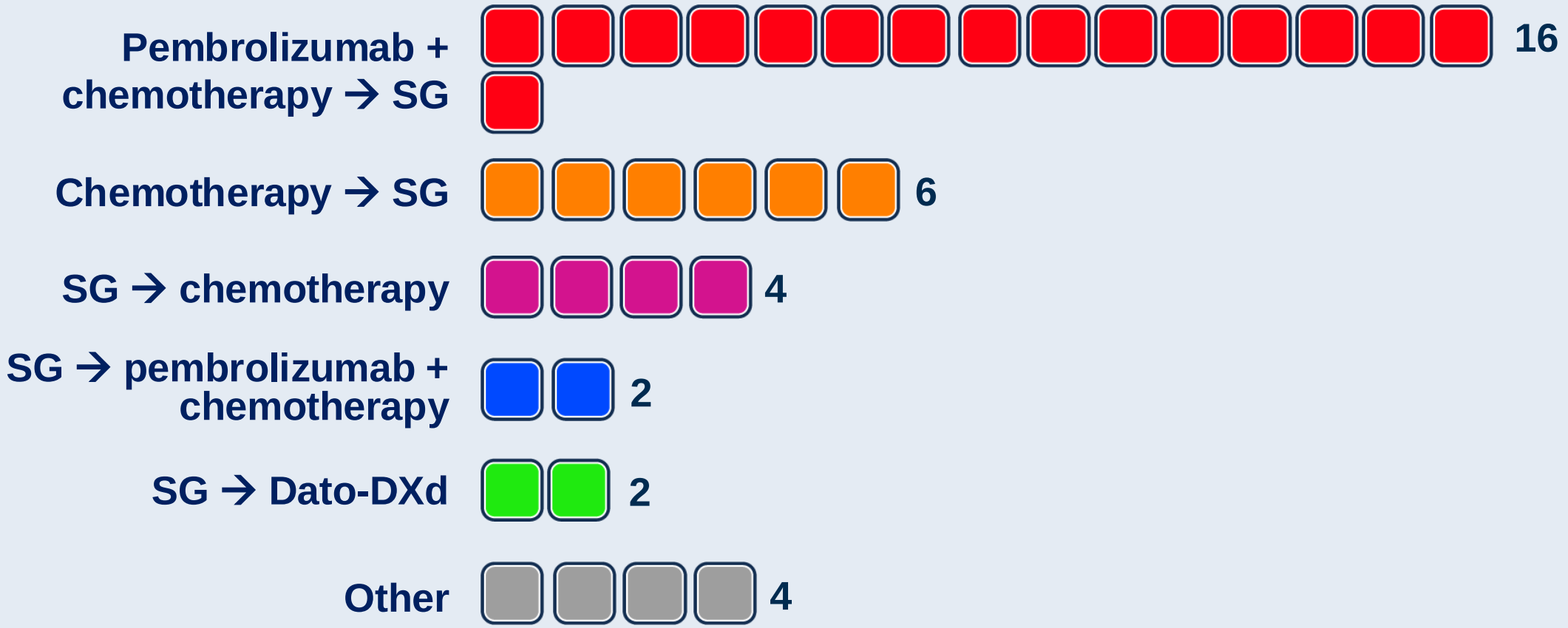

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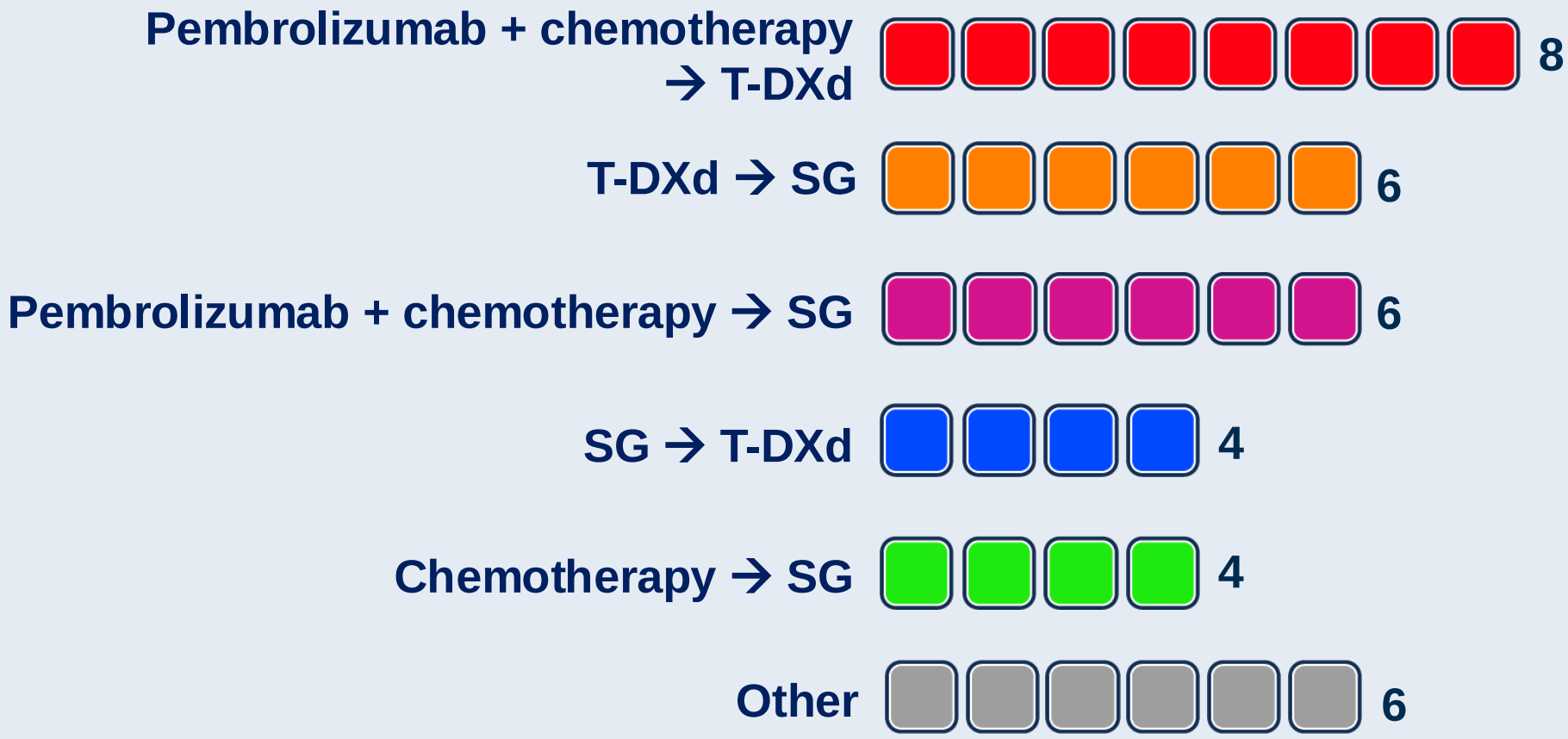

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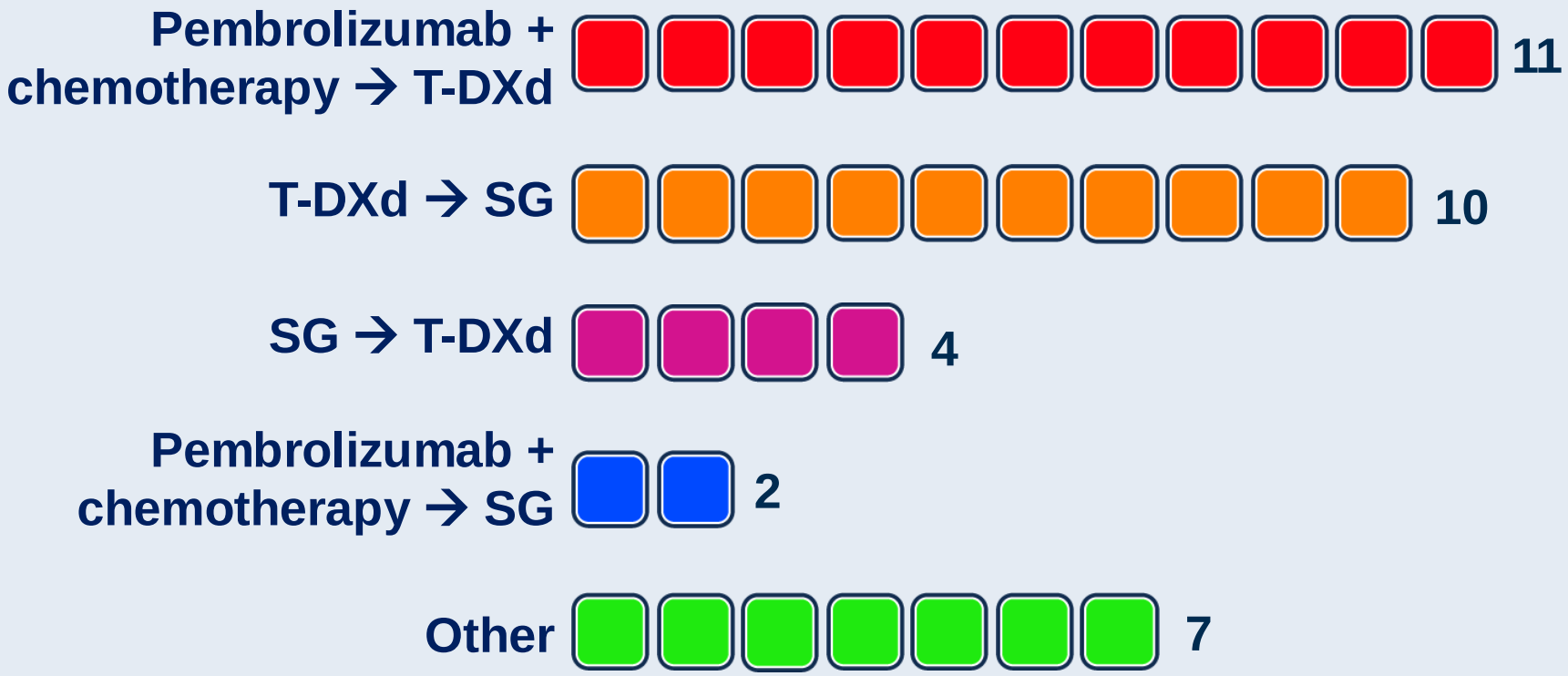

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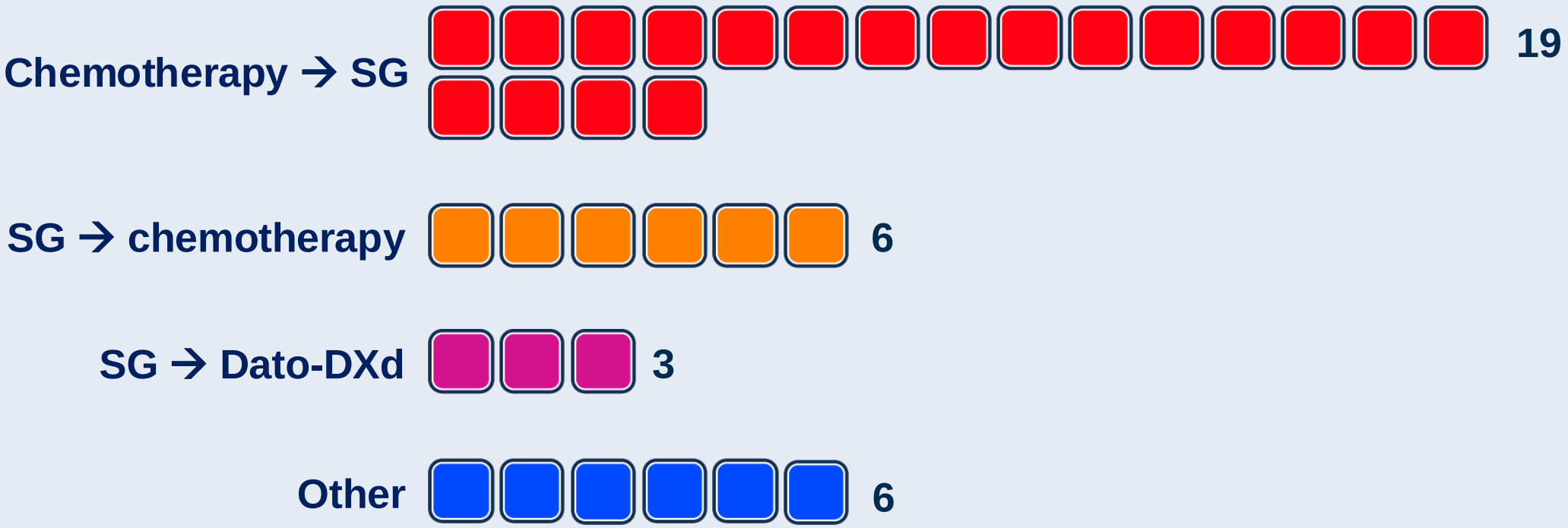
65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 12 months after completing (neo)adjuvant IO

HER2-negative (IHC 0)
PD-L1 CPS 0



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RTP RESEARCH TO PRACTICE

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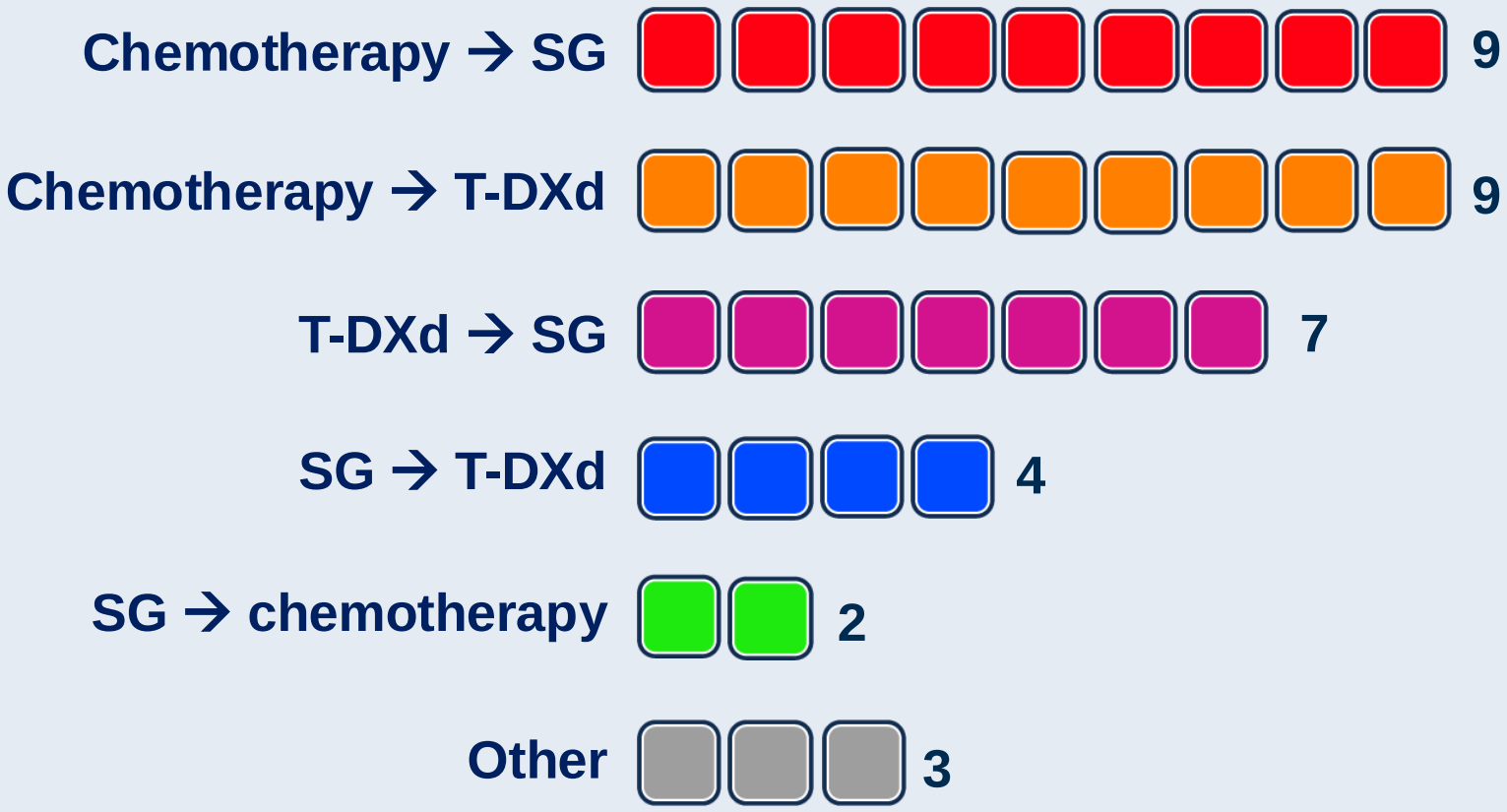

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65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 12 months after completing (neo)adjuvant IO

HER2 low (IHC 1+ or IHC 2+/ISH-negative)

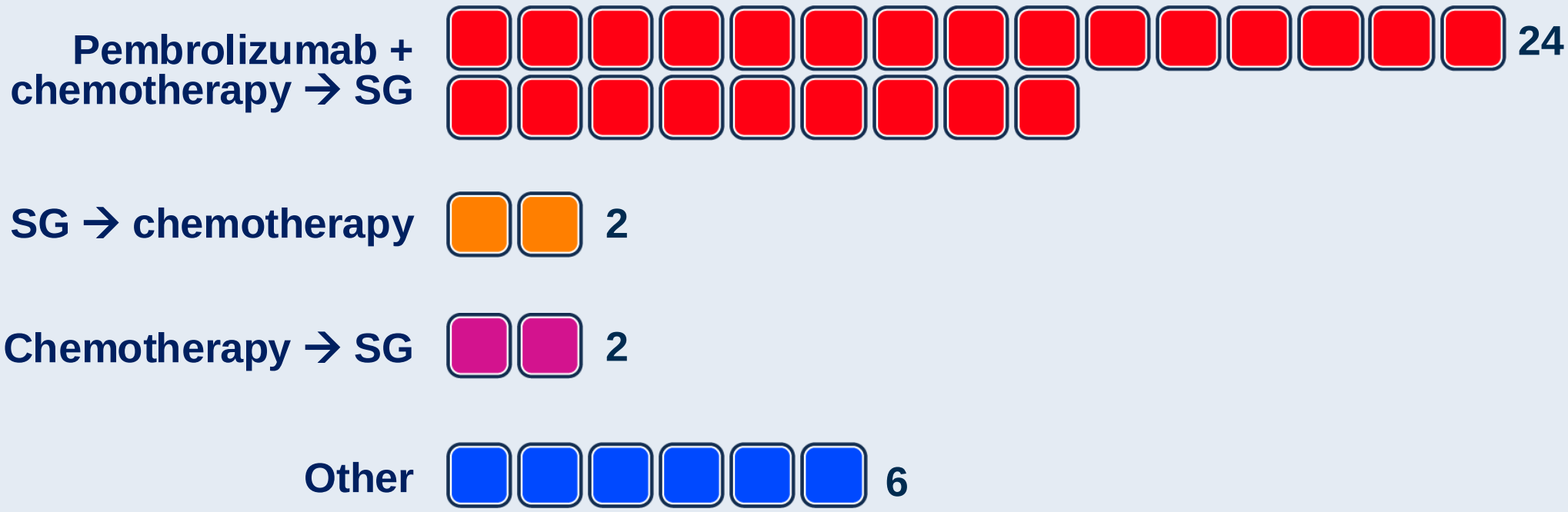
PD-L1 CPS 0

Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 12 months after completing (neo)adjuvant IO

HER2-negative (IHC 0)
PD-L1 CPS 50



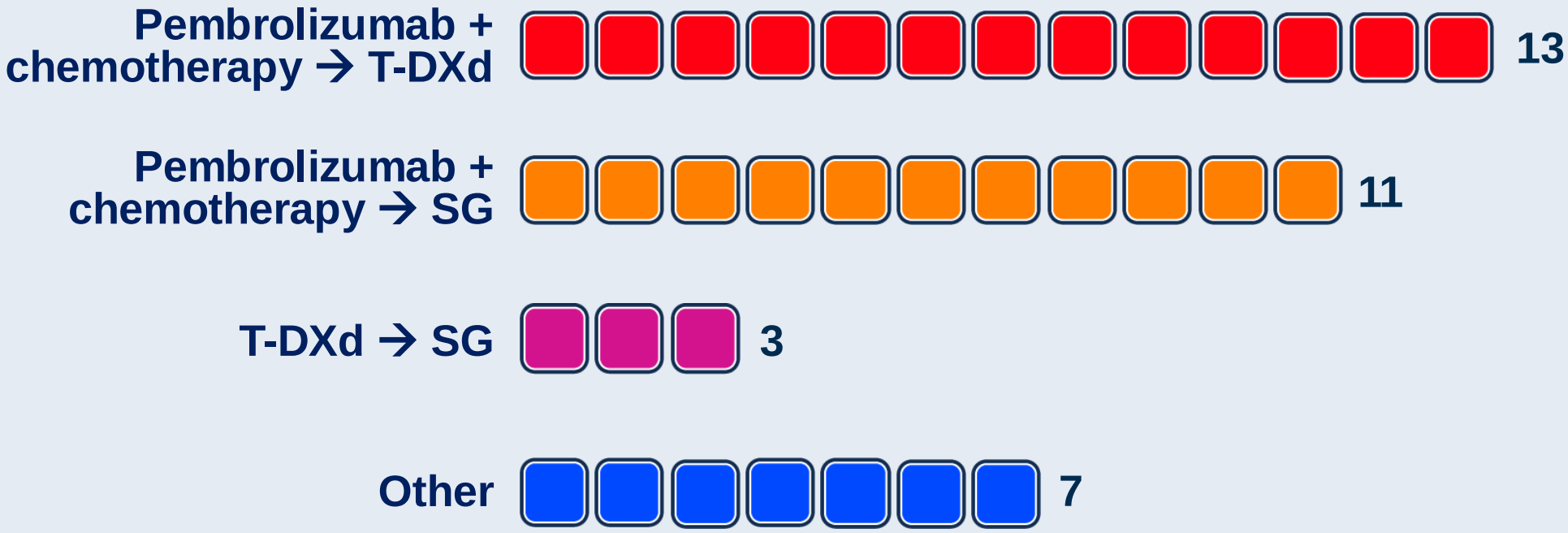
Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 12 months after completing (neo)adjuvant IO

HER2 ultralow (IHC >0 but <1+)

PD-L1 CPS 50

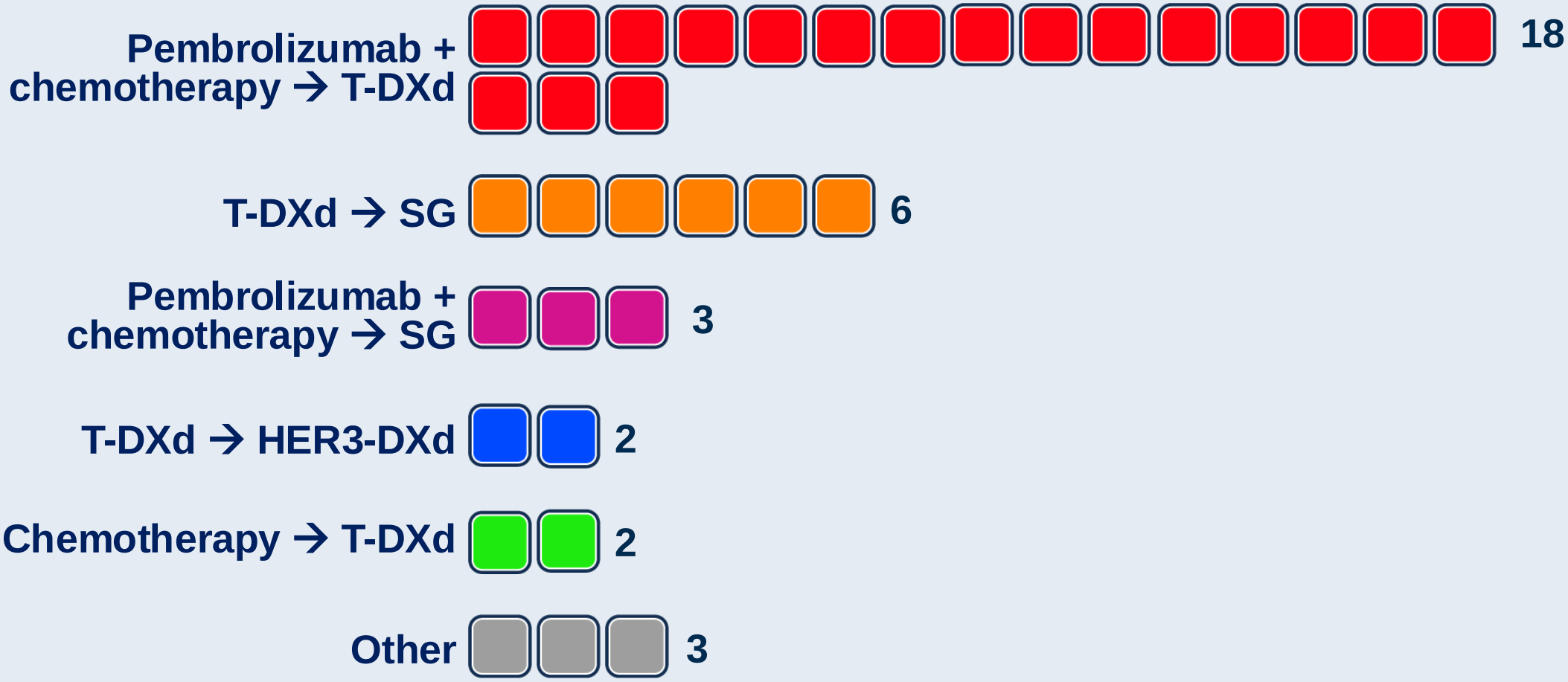


Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

65-year-old patient with metastatic ER-negative, BRCA-WT BC and disease progression 12 months after completing (neo)adjuvant IO

HER2 low (IHC 1+ or IHC 2+/ISH-negative)
PD-L1 CPS 50



Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

In general, when administering G-CSF to patients who are receiving sacituzumab govitecan (SG), what is your preferred agent and schedule?

- G-CSF days 9-20
- Pegfilgrastim
- Pegfilgrastim after day 8 of treatment
- Filgrastim day 9 of cycle
- Filgrastim days 2-4
- 2-3 days after each dose
- Long acting like pegfilgrastim and within 24 h of completion of therapy
- Filgrastim 480 mcg daily for 3 days
- Pegfilgrastim day 9
- PRN filgrastim
- Short acting
- Pegfilgrastim following treatment
- Long acting growth factor after day 8
- Pegfilgrastim or biosimilar day 8 of 21-day cycle
- Pegfilgrastim
- Pegfilgrastim day 9
- Pegfilgrastim
- Pegfilgrastim
- Pegfilgrastim day 9
- Pegfilgrastim q21d
- Pegfilgrastim
- Filgrastim daily x 5 after day 1 and day 8
- Pegfilgrastrim
- Long acting G-CSF: pegfilgrastim day 8
- Day 8 G-CSF and SG on days 1, 8
- Pegfilgrastrim after each dose

Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

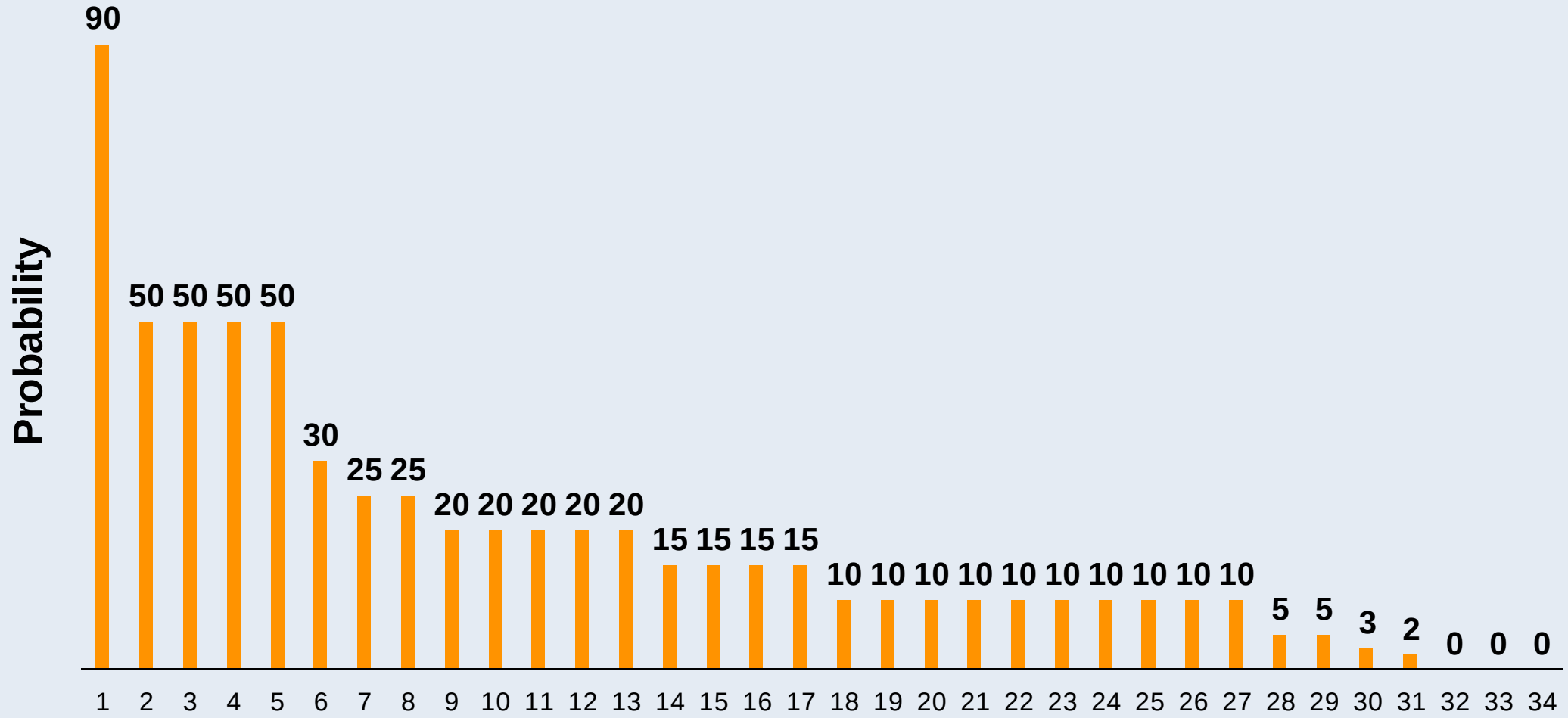
In general, when administering G-CSF to patients who are receiving sacituzumab govitecan, what is your preferred agent and schedule? (Continued)

- Filgrastim
- Pegfilgrastrim day 9
- Filgrastim 300 or 480 mcg sc daily till total WBC over 10,000
- I actually give alternate weeks of sacituzumab — Day 1 and 15 — and most of my younger patients do well on this schedule. If I need to give G-CSF, I go to day 1 and 8 schedule and give it for 5-7 days on day 8
- Pegfilgrastrim or biosimilar
- Filgrastim daily x 5
- I have not administered sacituzumab govitecan

Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

What would you estimate is the likelihood that a patient receiving sacituzumab govitecan will need to have therapy discontinued because of tolerability issues?



Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

At what point in the treatment course do you discuss palliative care options with your patients with mTNBC?

- When options decrease and/or performance status/QoL decline
- When performance status does not allow further therapy or patient is tired of therapy
- Third line
- When their performance status does not allow treatment
- Palliative care should always be discussed with the patient at the beginning of treatment if it's of noncurative intent
- At diagnosis of metastatic disease
- Every line of progression
- At the beginning of treatment
- After third line
- After 4 lines depending on PS
- Depends on performance and SE of therapy
- First line mention
- Early as adjunct to palliative chemo/immunotherapy
- Usually after first progression
- Third line and beyond

Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

At what point in the treatment course do you discuss palliative care options with your patients with mTNBC? (Continued)

- From the beginning, start gradually broaching each visit
- At the time of metastatic diagnosis
- Fourth line, beyond
- After 4-5 lines of treatment, sooner if poor functional status
- After third line
- When they are too sick or do not want any more treatment. Has nothing to do with a line of therapy
- Usually in line 2-3
- At diagnosis of metastatic disease
- First line
- With poor performance status
- Poor performance status
- Start vague discussions at or during second line, depends on individual patient and tolerability also
- After progression on 3 to 4 lines of therapy
- Diagnosis, after 3 lines of therapy
- After second line therapy
- After 3 lines of treatment
- At the time of diagnosis and at every progression
- After third line
- From the get-go

Survey of 34 US-based general medical oncologists, November 2024

RTP RESEARCH TO PRACTICE

2022 July;387(3):217-26

The NEW ENGLAND JOURNAL of MEDICINE

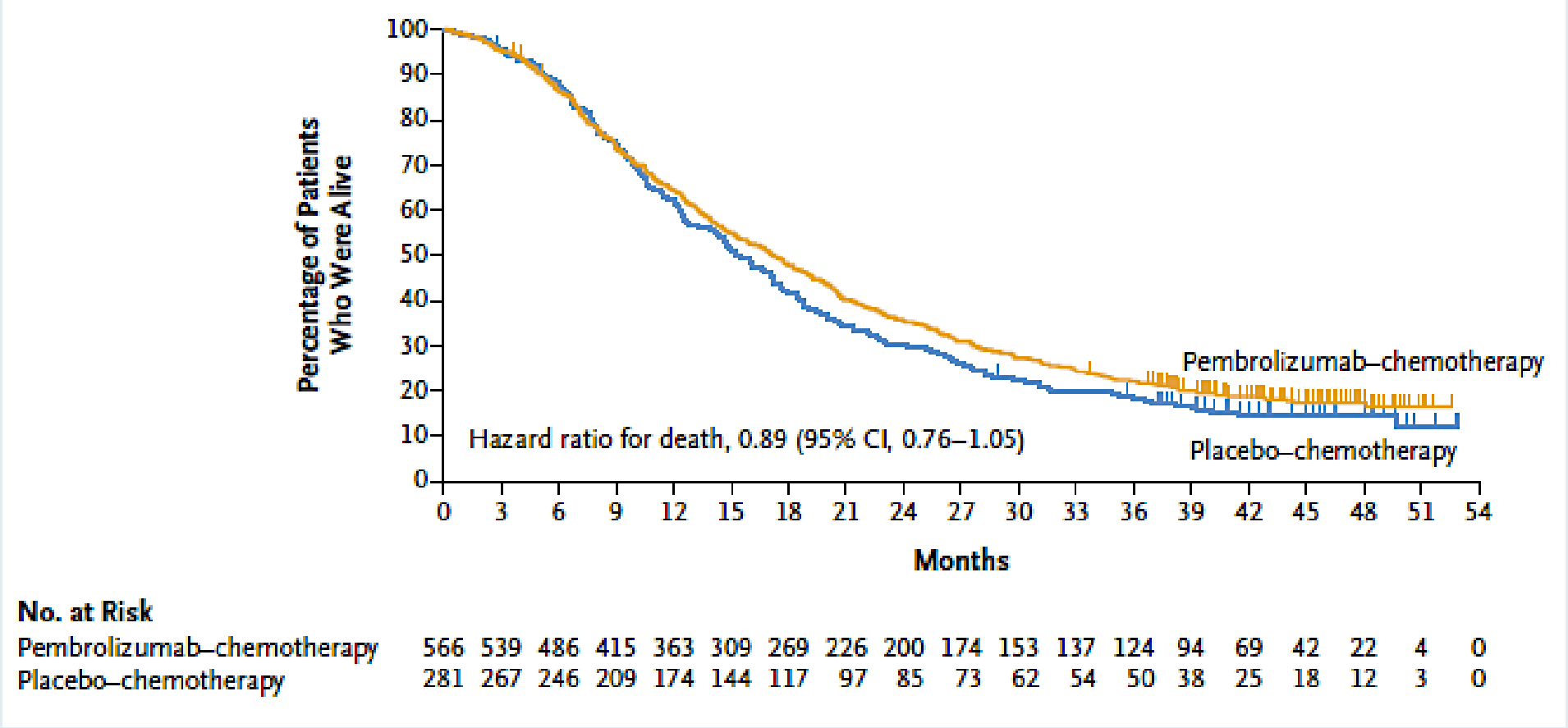
ORIGINAL ARTICLE

Pembrolizumab plus Chemotherapy in Advanced Triple-Negative Breast Cancer

J. Cortes, H.S. Rugo, D.W. Cescon, S.-A. Im, M.M. Yusof, C. Gallardo, O. Lipatov, C.H. Barrios, J. Perez-Garcia, H. Iwata, N. Masuda, M. Torregroza Otero, E. Gokmen, S. Loi, Z. Guo, X. Zhou, V. Karantza, W. Pan, and P. Schmid, for the KEYNOTE-355 Investigators*

RTP RESEARCH TO PRACTICE

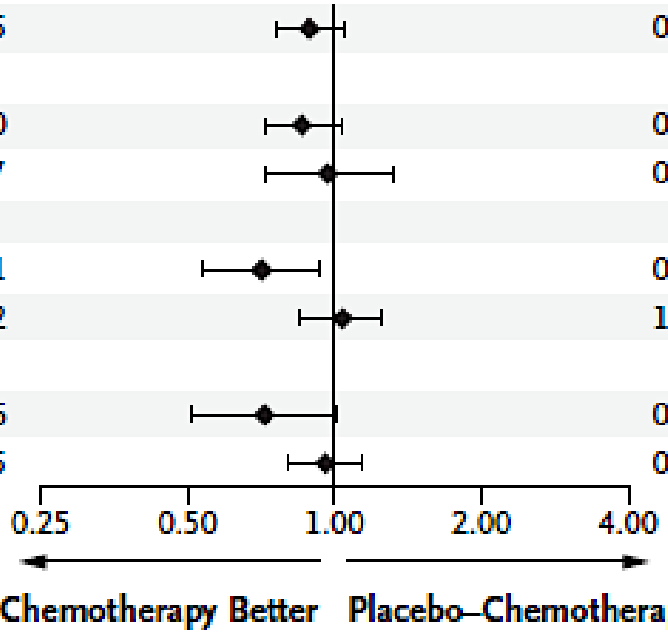
KEYNOTE-355 Trial: Overall Survival with Pembrolizumab and Chemotherapy as First-Line Therapy for mTNBC in the Intention-to-Treat Population



Cortes J et al. *N Engl J Med* 2022;387(3):217-26.

KEYNOTE-355: Overall Survival in Subgroups According to PD-L1 CPS Status at Baseline

Subgroup	No. of Patients	Median Overall Survival		Hazard Ratio for Death (95% CI)
		Pembrolizumab–chemotherapy	Placebo–chemotherapy	
		mo		
Overall	847	17.2	15.5	0.89 (0.76–1.05)
PD-L1 CPS cutoff of 1				
CPS ≥1	636	17.6	16.0	0.86 (0.72–1.04)
CPS <1	211	16.2	14.7	0.97 (0.72–1.32)
PD-L1 CPS cutoff of 10				
CPS ≥10	323	23.0	16.1	0.71 (0.54–0.93)
CPS <10	524	14.7	15.2	1.04 (0.85–1.26)
PD-L1 CPS cutoff of 20				
CPS ≥20	204	24.0	15.6	0.72 (0.51–1.01)
CPS <20	643	15.9	15.5	0.96 (0.80–1.14)



CPS = combined positive score

Cortes J et al. *N Engl J Med* 2022;387(3):217-26.

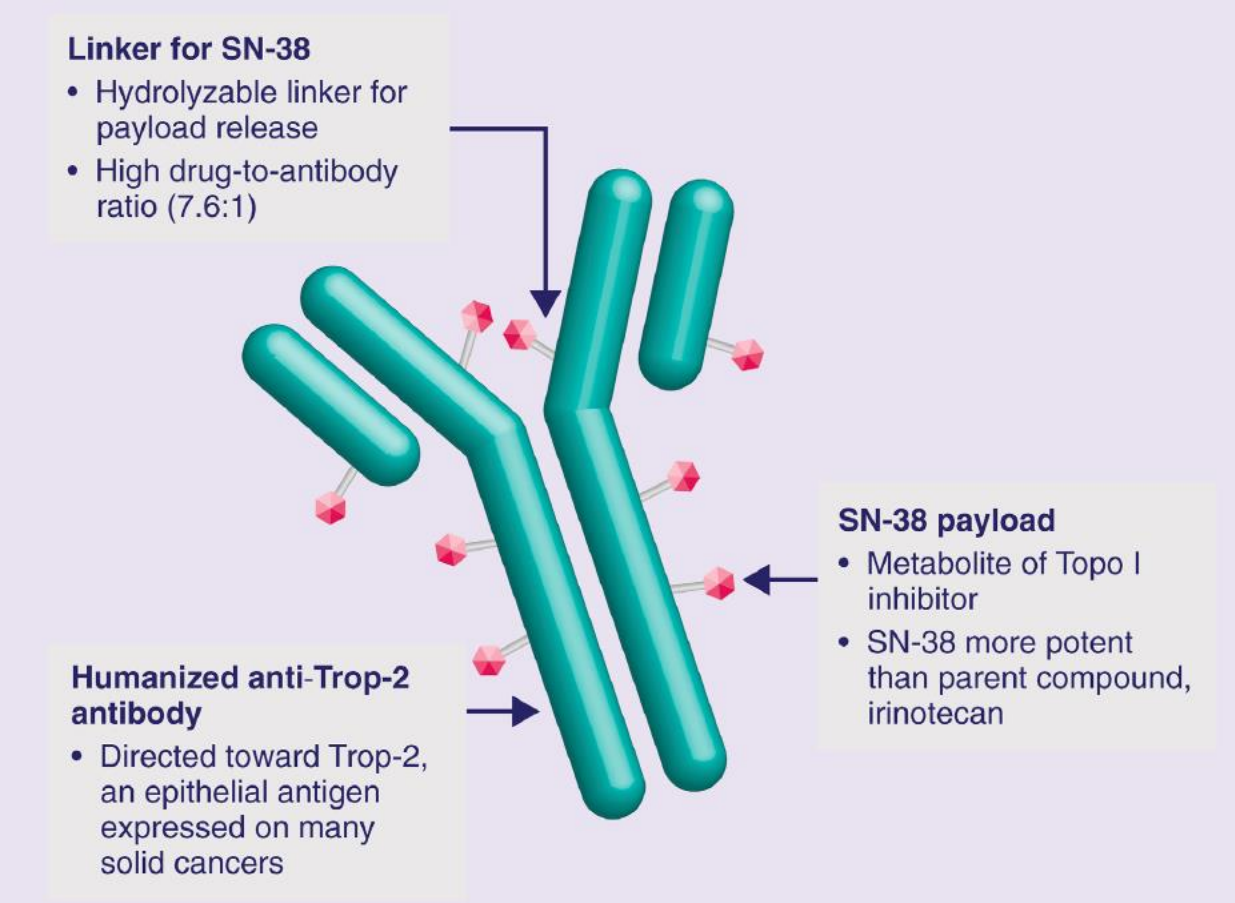
Ongoing Phase III Trials of Sacituzumab Govitecan in Earlier Lines of Therapy for Patients with TNBC

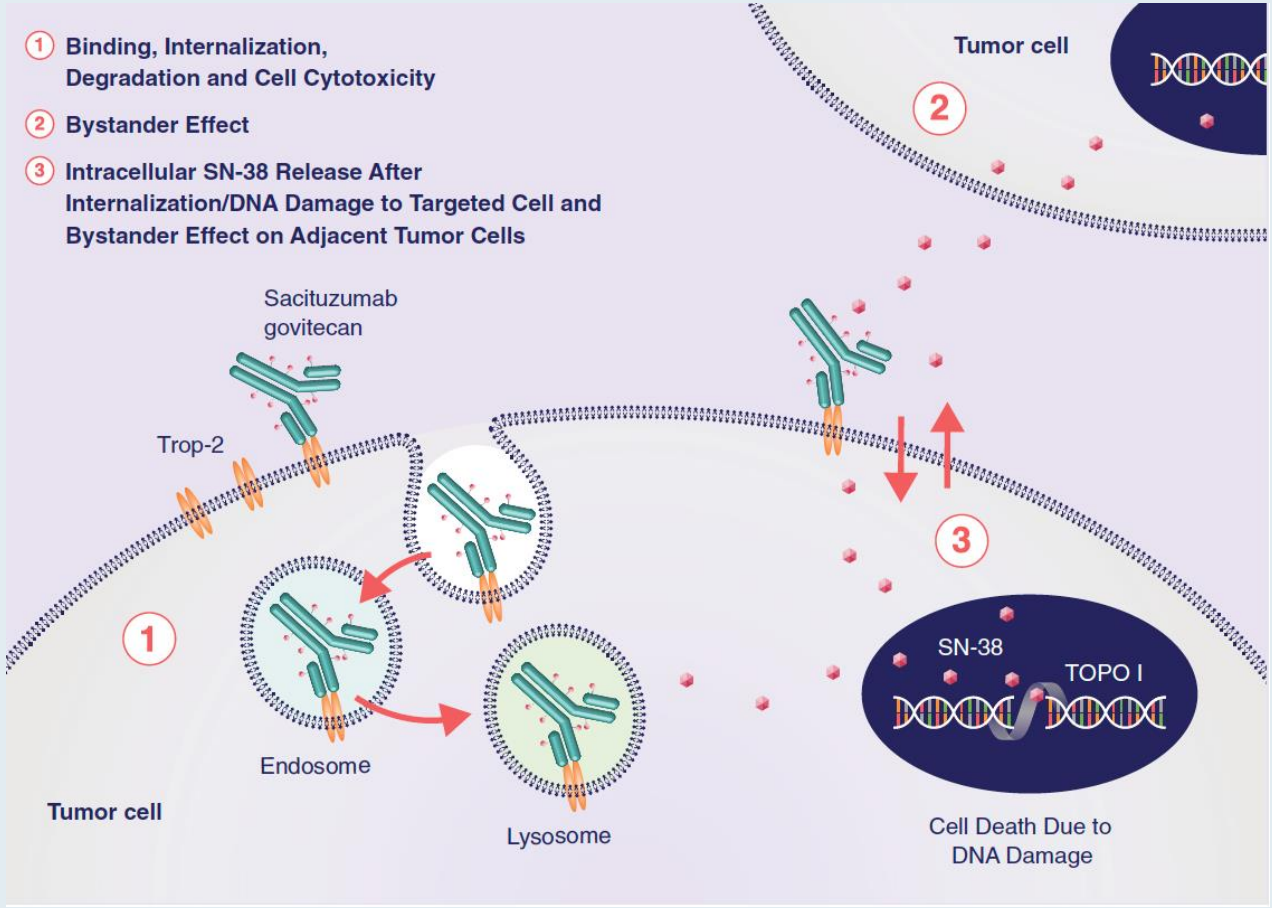
Study	N	Setting	Randomization	Est primary completion
ASCENT-03	540	Previously untreated locally advanced inoperable or metastatic TNBC with no PD-L1 expression or previously treated with immune checkpoint inhibitor and with PD-L1 expression	• Sacituzumab govitecan • Treatment of physician's choice	July 2028
ASCENT-04	440	Previously untreated locally advanced inoperable or metastatic TNBC with PD-L1 tumor expression	• Sacituzumab govitecan + pembrolizumab • Treatment of physician's choice	Feb 2027
ASCENT-05	1,514	TNBC with residual invasive disease after surgery and neoadjuvant therapy	• Sacituzumab govitecan + pembrolizumab • Treatment of physician's choice	June 2027
SASCIA	1,332	Postneoadjuvant in primary HER2-negative breast cancer with high relapse risk	• Sacituzumab govitecan • Treatment of physician's choice	March 2027

www.clinicaltrials.gov. Accessed October 2024.

RTP RESEARCH TO PRACTICE

Sacituzumab Govitecan Is a First-in-Class TROP2-Directed Antibody-Drug Conjugate





Rugo HS et al. *Future Oncol* 2020;16(12):705-15.

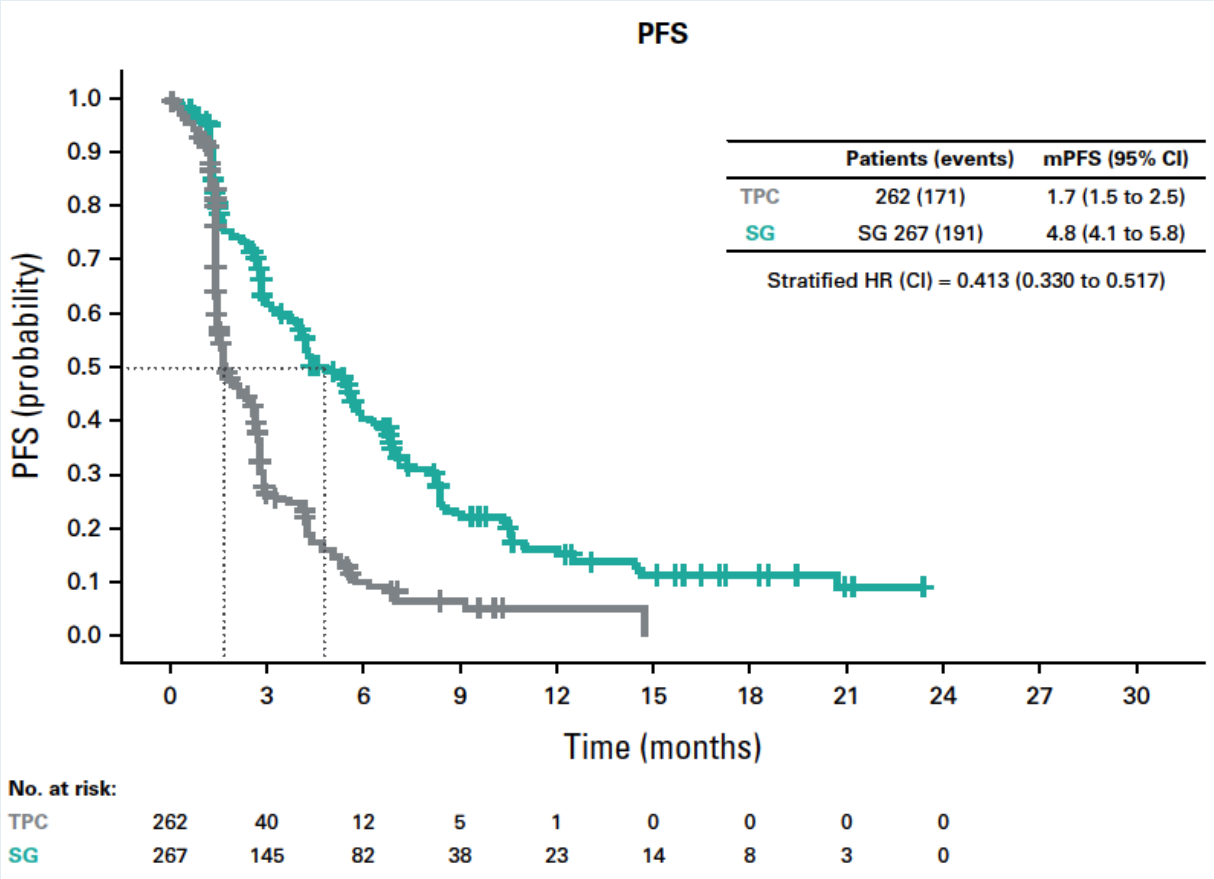
Final Results From the Randomized Phase III ASCENT Clinical Trial in Metastatic Triple-Negative Breast Cancer and Association of Outcomes by Human Epidermal Growth Factor Receptor 2 and Trophoblast Cell Surface Antigen 2 Expression

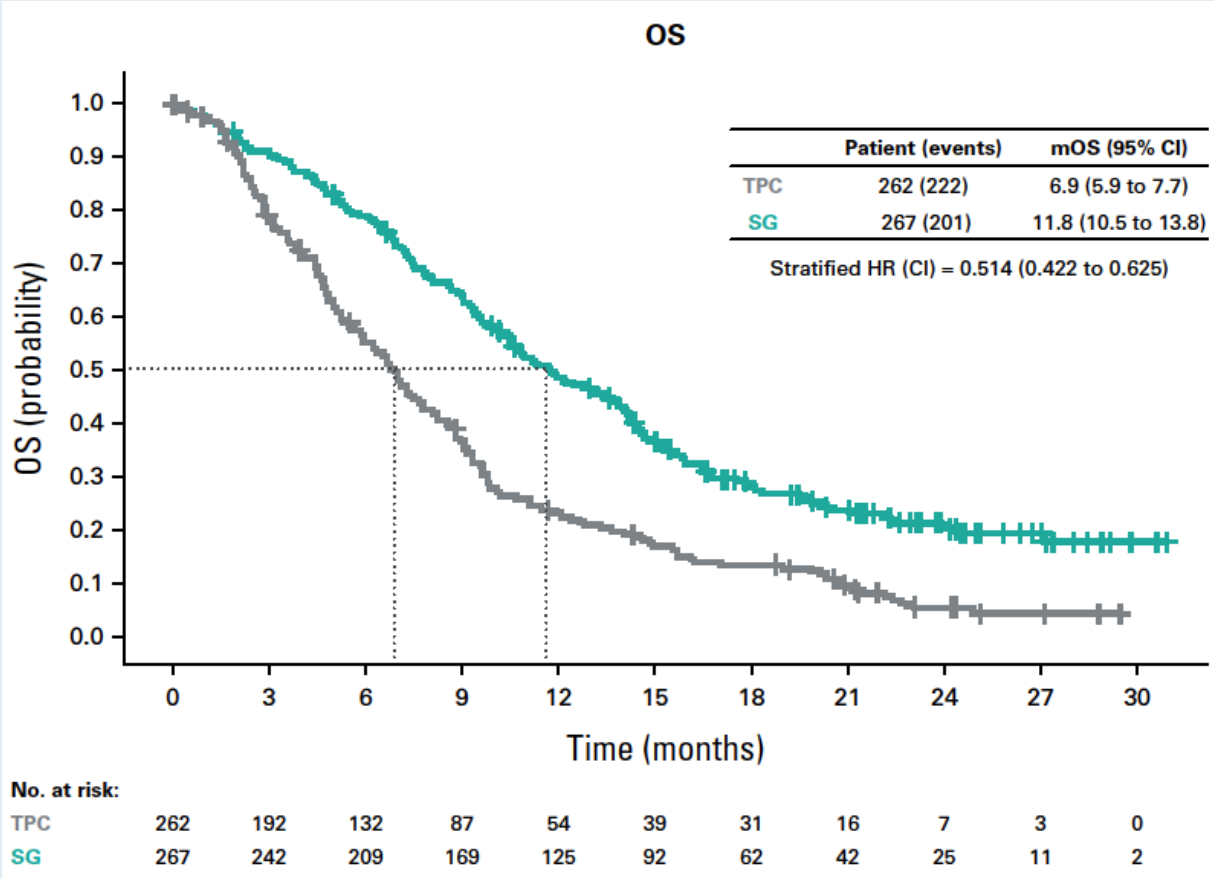
Aditya Bardia, MD, MPH[1]; Hope S. Rugo, MD[2]; Sara M. Tolaney, MD, MPH[3]; Delphine Loirat, PhD, MD[4]; Kevin Punie, MD[5]; Mafalda Oliveira, MD, PhD[6]; Adam Brufsky, MD, PhD[7]; Kevin Kalinsky, MD, MS[8]; Javier Cortés, MD, PhD[9]; Joyce O' Shaughnessy, MD[10]; Véronique Diéras, MD, MPH[11]; Lisa A. Carey, MD, ScM[12]; Luca Gianni, MD[13]; Martine Piccart-Gebhart, MD, PhD[14]; Sibylle Loibl, MD, PhD[15]; Oh Kyu Yoon, PhD, MBA[16]; Yang Pan, PhD[16]; Scott Hofsess, MS[17]; See-Chun Phan, MD[16]; and Sara A. Hurvitz, MD, FACP[18]

J Clin Oncol 2024 May 20;42(15):1738-44

RTP RESEARCH TO PRACTICE

ASCENT: Final Survival Results





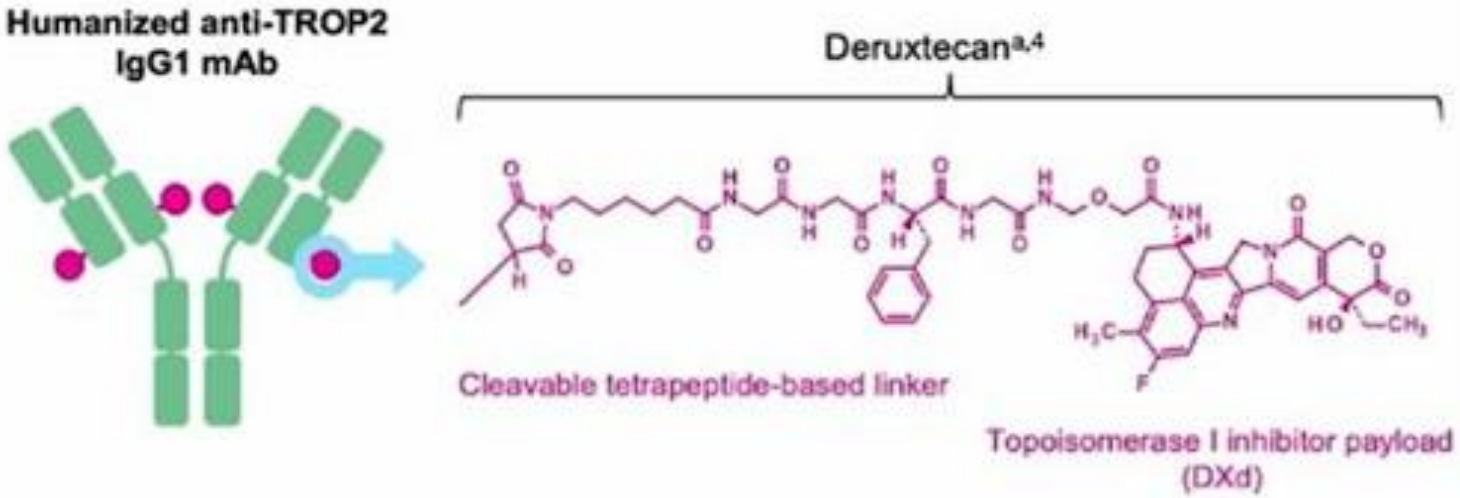
PFS = progression-free survival; TPC = treatment of physician's choice; SG = sacituzumab govitecan; OS = overall survival

Bardia A et al. *J Clin Oncol* 2024 May 20;42(15):1738-44.

Datopotamab Deruxtecan (Dato-DXd): Mechanism of Action

Dato-DXd is an ADC with 3 components[1,2]:

- A humanized anti-TROP2 IgG1[3] monoclonal antibody attached to:
- A topoisomerase I inhibitor payload, an exatecan derivative, via
- A tetrapeptide-based cleavable linker



Payload mechanism of action: topoisomerase I inhibitor[b,1]
High potency of payload[b,2]
Optimized drug to antibody ratio ≈4[b,c,1]
Payload with short systemic half-life[b,c,2]
Stable linker-payload[b,2]
Tumor-selective cleavable linker[b,2]
Bystander antitumor effect[b,2,5]

Krop I et al. San Antonio Breast Cancer Symposium 2021;Abstract GS1-05.

RTP RESEARCH TO PRACTICE

Research article

Datopotamab deruxtecan: A novel antibody drug conjugate for triple-negative breast cancer

Francesca Matilde Schipilliti [a,†], Denise Drittone [a,†], Federica Mazzuca [b], Daniele La Forgia [c], Deniz Can Guven [d,1], Alessandro Rizzo [c,*,1]

Heliyon **2024 March 22;10(7)**

RTP RESEARCH TO PRACTICE

Summary of Available Data from the TROPION-PanTumor01 and BEGONIA Trials of Dato-DXd for mTNBC

NCT Number/Trial name	Trial Design/Patient Population	Characteristics	Number of pts	Intervention	Primary endpoint	Clinical Trial Data	Safety
NCT03401385, TROPION-PanTumor01	FIH trial with Datopotamab deruxtecan in refractory metastatic TNBC (N = 44)	A Phase 1, Two-Part, Multicenter, Open-Label, Multiple-Dose, First-in-Human Study of Dato-DXd in Patients With Advanced/ Metastatic Solid Tumors	770	Drug: Datopotamab Deruxtecan (Dato-DXd) Drug: Steroid Containing Mouthwash Other: Non-Steroid Containing Mouthwash	Safety and tolerability	ORR 32% (ORR-44% in Topo I inhibitors-naive patients)	G3 AEs were observed in 52% of pts. Most common TEAEs (any grade, grade ≥3) were stomatitis (73%, 11%), nausea (66%, 2%), and vomiting (39%, 5%)
NCT03742102 BEGONIA trial	Phase Ib/II platform trial with Datopotamab deruxtecan + durvalumab in first-line metastatic TNBC (N = 29)	Multi-center, Open-Label, Platform Study Evaluating the Efficacy and Safety of Durvalumab in Combination With Novel Oncology Therapies for First-Line Treatment in Patients With Metastatic TNBC	210	Drug: Durvalumab Drug: Capivasertib Drug: Oleclumab	Safety and tolerability	ORR 79% Median DoR not reached Responses were seen regardless of PD-L1 expression	G3/4 AEs were observed in 36% of pts. Most common TEAEs (any grade, grade ≥3) were gastrointestinal (nausea in 26 patients [55%] and stomatitis in 24 patients [51%])

Schipillti FM et al. *Heliyon* 2024 March 22;10(7).

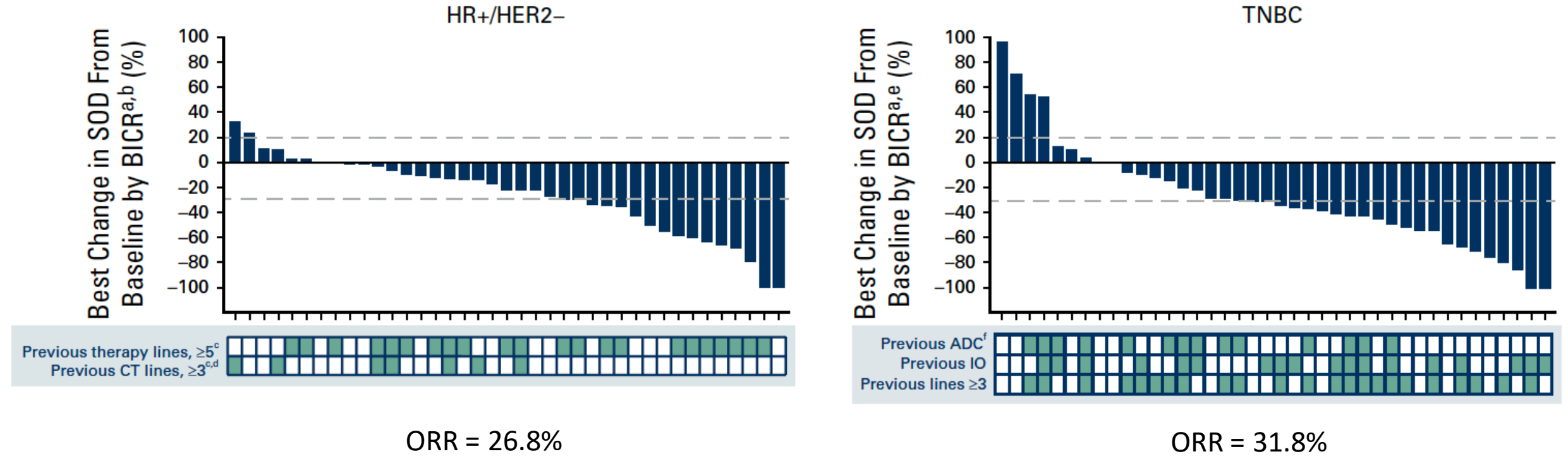
Datopotamab Deruxtecan in Advanced or Metastatic HR+/HER2– and Triple-Negative Breast Cancer: Results From the Phase I TROPION-PanTumor01 Study

Aditya Bardia, MD, PhD[1]; Ian E. Krop, MD, PhD[2,3]; Takahiro Kogawa, MD, PhD[4]; Dejan Juric, MD[1]; Anthony W. Tolcher, MD[5,6,7]; Erika P. Hamilton, MD[8,9]; Toru Mukohara, MD, DMedSci[10]; Aaron Lisberg, MD[11]; Toshio Shimizu, MD, PhD[12,13]; Alexander I. Spira, MD[14]; Junji Tsurutani, MD, PhD[15]; Senthil Damodaran, MD, PhD[16]; Kyriakos P. Papadopoulos, MD[17]; Jonathan Greenberg, MD, MA, BA[18,19]; Fumiaki Kobayashi, PhD, MS[20]; Hong Zebger-Gong, MD, PhD[19]; Rie Wong, BS[21]; Yui Kawasaki, PhD[18]; Tadakatsu Nakamura, MS[20]; and Funda Meric-Bernstam, MD[16]

J Clin Oncol 2024 July 1;42(19):2281-94

RTP RESEARCH TO PRACTICE

TROPION-PanTumor01: Antitumor Activity of Dato-DXd in HR-Positive, HER2-Negative and Triple-Negative Breast Cancer



SOD = sum of diameters; BICR = blinded independent central review; CT = chemotherapy; ADC = antibody-drug conjugate; IO = immuno-oncology; ORR = overall response rate

Bardia A et al. *J Clin Oncol* 2024 July 1;42(19):2281-94.

RTP RESEARCH TO PRACTICE

Ongoing Phase III Trials of Dato-DXd for TNBC

Study	N	Setting	Randomization	Est primary completion
TROPION-Breast02	600	Previously untreated HR-negative, HER2-negative, locally advanced unresectable or metastatic TNBC	• Dato-DXd • Investigator's choice of chemotherapy	Dec 2025
TROPION-Breast05	625	PD-L1 positive locally recurrent inoperable or metastatic TNBC	• Dato-DXd +/- durvalumab • Investigator choice of chemotherapy + pembrolizumab	Sept 2026
TROPION-Breast04	1,728	Previously untreated TNBC or HR-low/HER2-negative breast cancer	• Dato-DXd + durvalumab → durvalumab +/- chemotherapy • Pembrolizumab + chemotherapy → pembro +/- chemo	March 2028
TROPION-Breast03	1,075	Stage I-III TNBC without pathological complete response following neoadjuvant therapy	• Dato-DXd +/- durvalumab • Investigator’s choice of chemotherapy	Sept 2027

www.clinicaltrials.gov. Accessed April 2024.

RTP RESEARCH TO PRACTICE

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JULY 7, 2022 VOL. 387 NO. 1

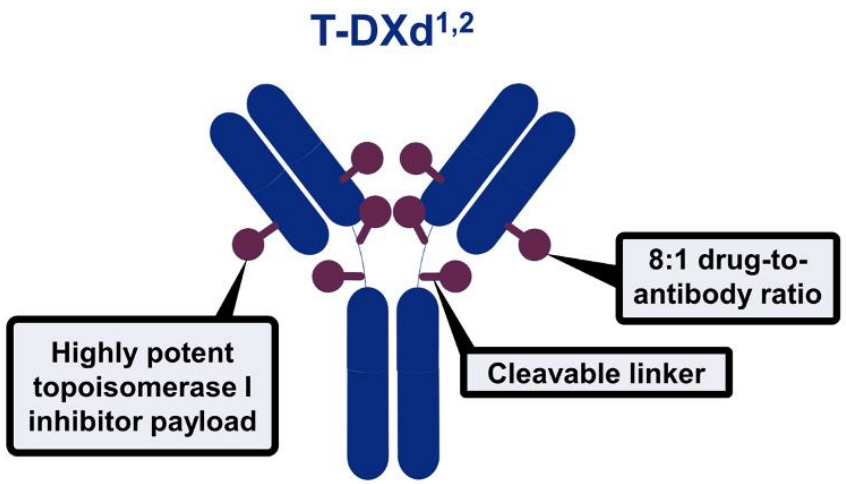
Trastuzumab Deruxtecan in Previously Treated HER2-Low Advanced Breast Cancer

S. Modi, W. Jacot, T. Yamashita, J. Sohn, M. Vidal, E. Tokunaga, J. Tsurutani, N.T. Ueno, A. Prat, Y.S. Chae, K.S. Lee, N. Niikura, Y.H. Park, B. Xu, X. Wang, M. Gil-Gil, W. Li, J.-Y. Pierga, S.-A. Im, H.C.F. Moore, H.S. Rugo, R. Yerushalmi, F. Zagouri, A. Gombos, S.-B. Kim, Q. Liu, T. Luo, C. Saura, P. Schmid, T. Sun, D. Gambhire, L. Yung, Y. Wang, J. Singh, P. Vitazka, G. Meinhardt, N. Harbeck, and D.A. Cameron, for the DESTINY-Breast04 Trial Investigators*

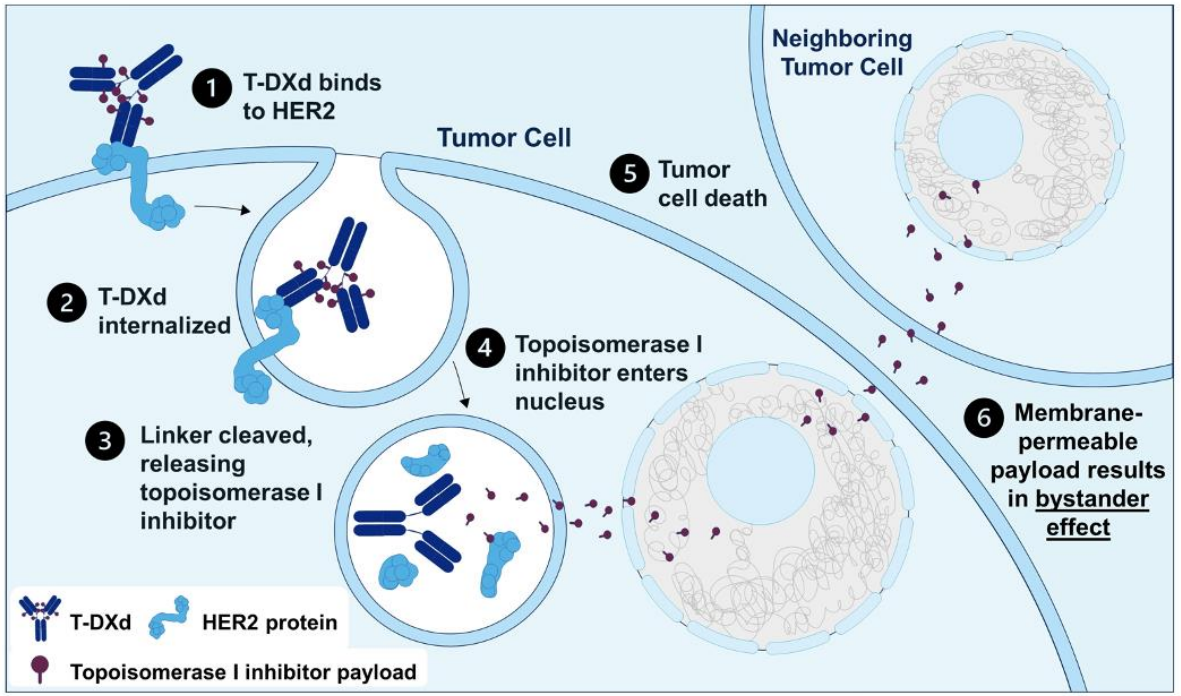
9-20

RTP RESEARCH TO PRACTICE

T-DXd Mechanism of Action, Bystander Effect and Rationale for Targeting HER2-Low Breast Cancer



Internalization of T-DXd leads to release of the DXd payload and subsequent cell death in the target tumor cell and neighboring tumor cells through the bystander effect[1,2]



Adapted with permission from Modi S, et al. *J Clin Oncol* 2020;38:1887-96. CC BY ND 4.0.

- **Results from a phase 1b study have reported efficacy of T-DXd in heavily pretreated patients (N = 54) with HER2-low mBC, with a mPFS of 11.1 months and an ORR of 37.0%[3]**

mPFS = median progression-free survival; ORR = overall response rate

Modi S et al. *N Engl J Med* 2022;387(1):9-20.

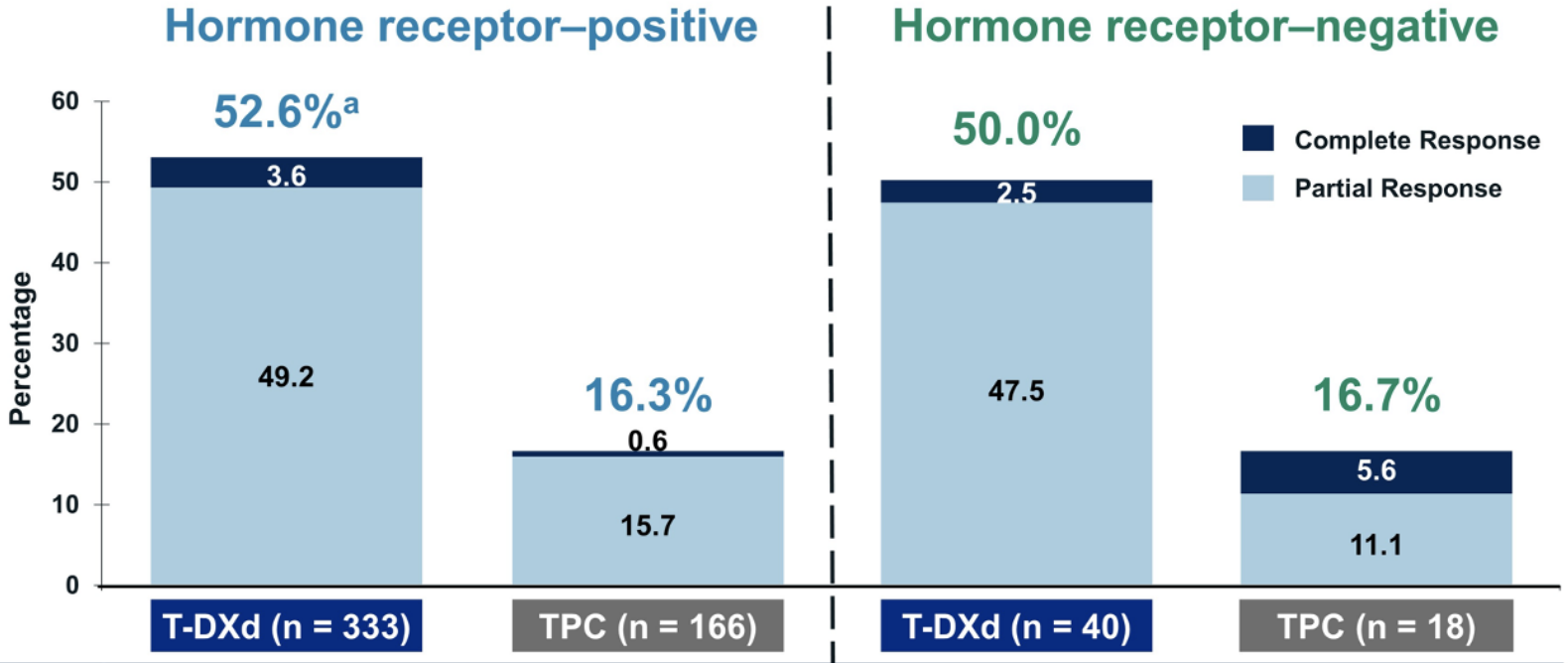
DESTINY-Breast04 Trial: Response and Survival with T-DXd for the Hormone-Receptor-Negative Population

	All patients			Hormone-receptor negative		
	T-DXd (N = 373)	TPC (N = 184)	HR (*p*-value)	T-DXd (N = 40)	TPC (N = 18)	Hazard ratio
Median PFS	9.9 mo	5.1 mo	0.5 (<0.001)	8.5 mo	2.9 mo	0.46
Median OS	23.4 mo	16.8 mo	0.64 (0.001)	18.2 mo	8.3 mo	0.48
Objective response rate	52.3%	16.3%	—	50.0%	16.7%	—

Modi S et al. *N Engl J Med* 2022;387(1):9-20.

RTP RESEARCH TO PRACTICE

DESTINY-Breast04: Confirmed Objective Response Rate



	T-DXd (n = 333)	TPC (n = 166)	T-DXd (n = 40)	TPC (n = 18)
Progressive disease, %	7.8	21.1	12.5	33.3
Not evaluable, %	4.2	12.7	7.5	5.6
Clinical benefit rate,[b] %	71.2	34.3	62.5	27.8
Duration of response, months	10.7	6.8	8.6	4.9

Modi S et al. ASCO 2022;Abstract LBA3. Modi S et al. *N Engl J Med* 2022;387(1):9-20.

MADRID 2023 ESMO congress

Abstract 376O

Trastuzumab Deruxtecan (T-DXd) Versus Treatment of Physician's Choice (TPC) in Patients With HER2-Low Unresectable and/or Metastatic Breast Cancer: Updated Survival Results of the Randomized, Phase 3 DESTINY-Breast04 Study

Presentation 376O

Shanu Modi,[1] William Jacot, Hiroji Iwata, Yeon Hee Park, Maria Jesus Vidal Losada, Wei Li, Junji Tsurutani, Khalil Zaman, Naoto Ueno, Aleix Prat, Konstantinos Papazisis, Hope S. Rugo, Nadia Harbeck, Seock-Ah Im, Michelino De Laurentis, Cecilia Orbegoso Aguilar, Lotus Yung, Fu-Chih Cheng, Yingkai Cheng, David Cameron

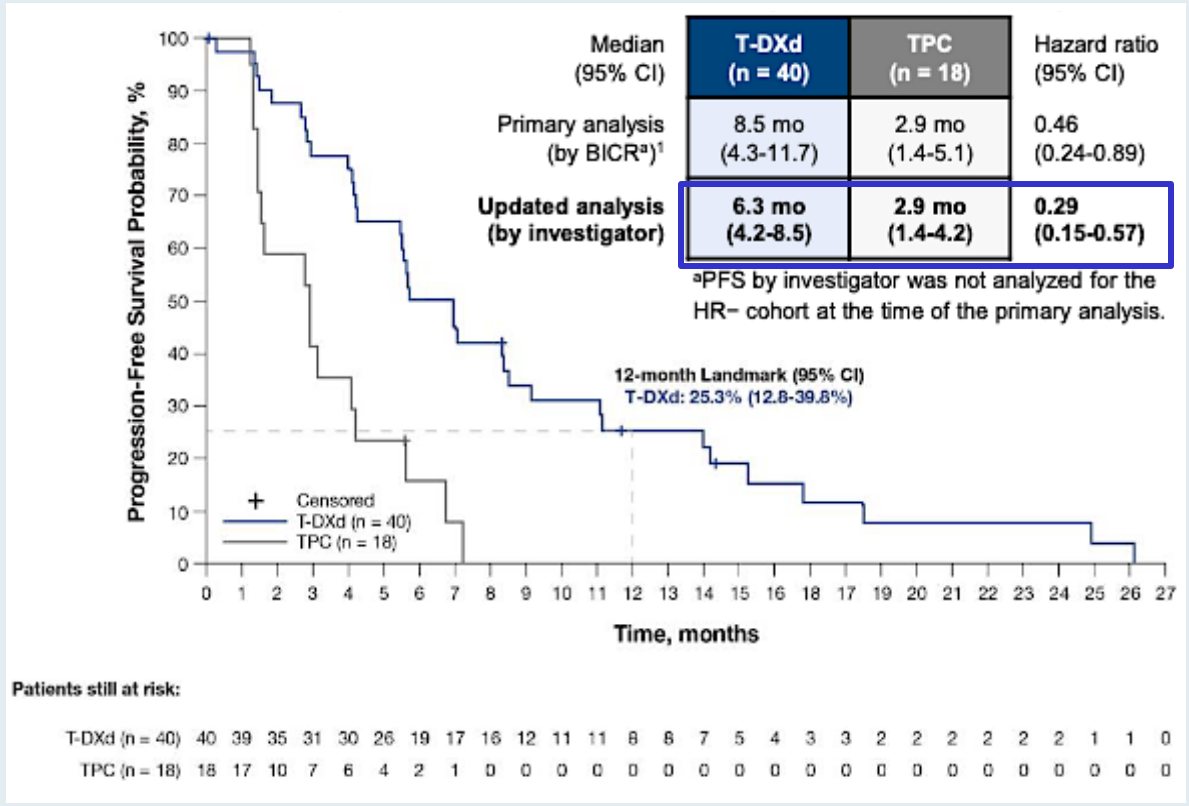
On behalf of the DESTINY-Breast04 investigators

[1]Memorial Sloan Kettering Cancer Center, New York, NY, USA

Madrid, Spain, October 20-24, 2023

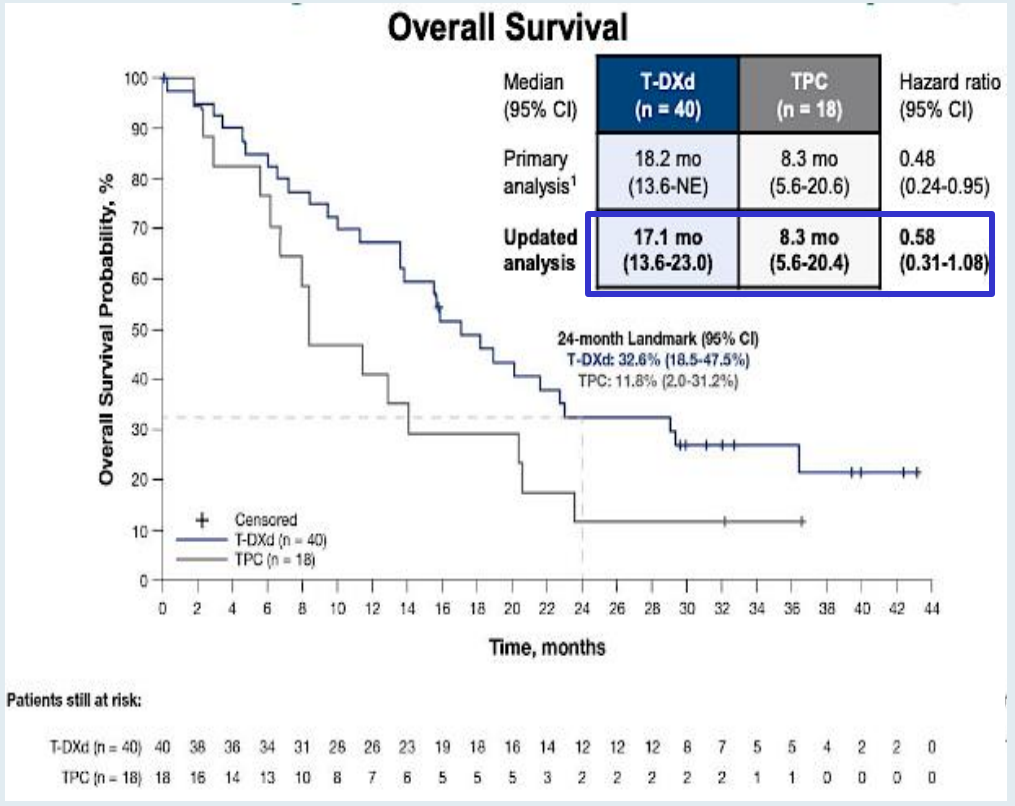
RTP RESEARCH TO PRACTICE

DESTINY-Breast04: Final Survival Analyses



Median (95% CI)	T-DXd (n = 40)	TPC (n = 18)	Hazard ratio (95% CI)
Primary analysis (by BICR[a])[1]	8.5 mo (4.3-11.7)	2.9 mo (1.4-5.1)	0.46 (0.24-0.89)
Updated analysis (by investigator)	**6.3 mo (4.2-8.5)**	**2.9 mo (1.4-4.2)**	**0.29 (0.15-0.57)**

[a]PFS by investigator was not analyzed for the HR− cohort at the time of the primary analysis.



Median (95% CI)	T-DXd (n = 40)	TPC (n = 18)	Hazard ratio (95% CI)
Primary analysis[1]	18.2 mo (13.6-NE)	8.3 mo (5.6-20.6)	0.48 (0.24-0.95)
Updated analysis	**17.1 mo (13.6-23.0)**	**8.3 mo (5.6-20.4)**	**0.58 (0.31-1.08)**

BICR = blinded independent central review; TPC = treatment of physician's choice

Modi S et al. ESMO 2023;Abstract 376O.

European Journal of Cancer 178 (2023) 23–33

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.ejcancer.com

Original Research

Health-related quality of life in the phase III ASCENT trial of sacituzumab govitecan versus standard chemotherapy in metastatic triple-negative breast cancer

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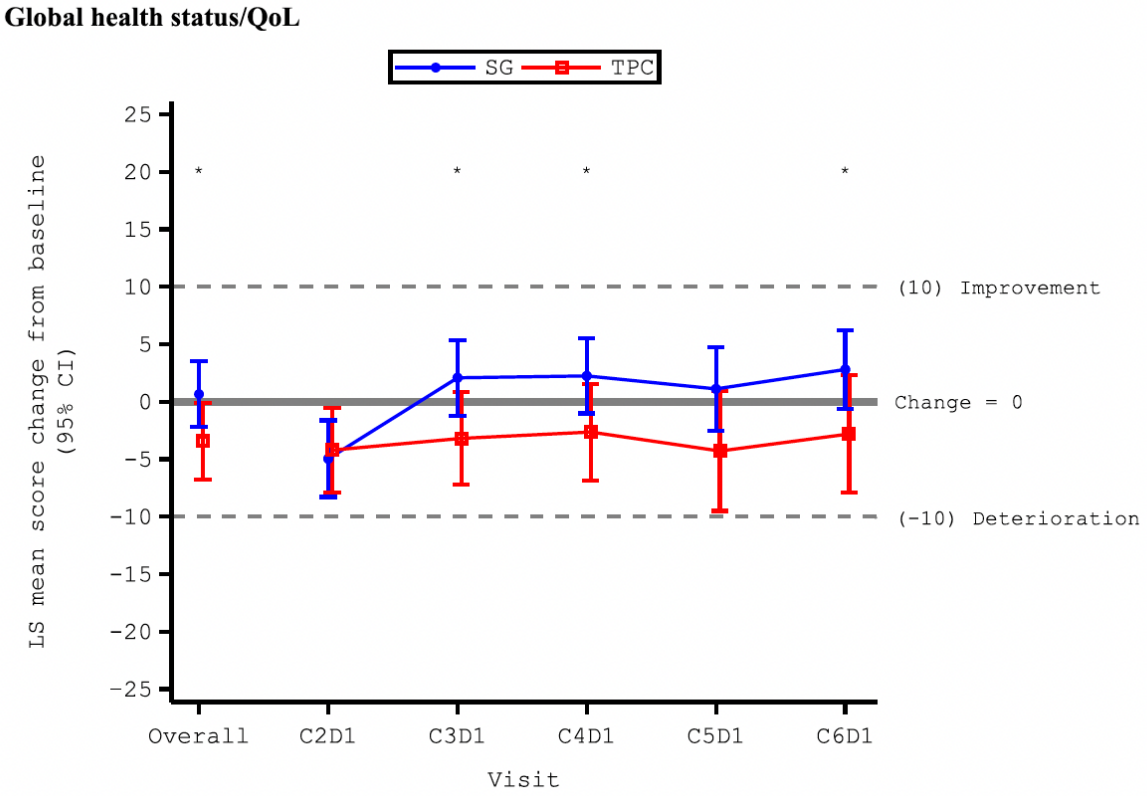
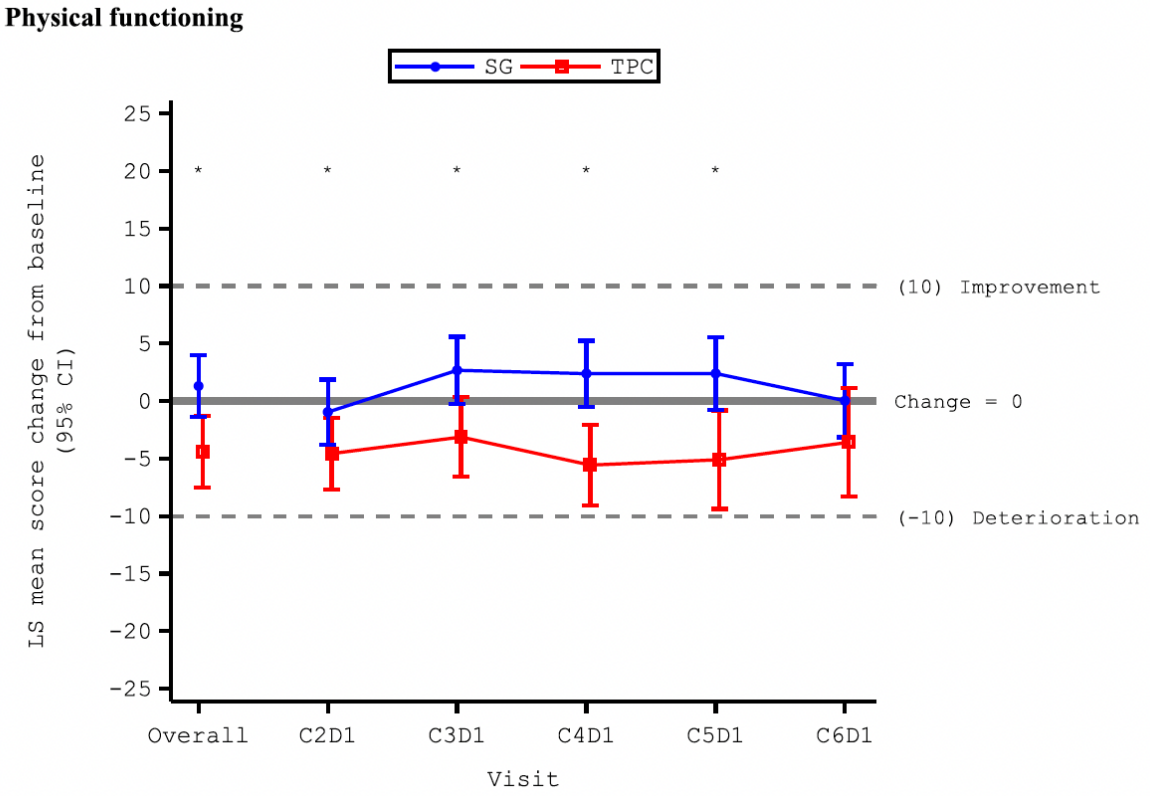
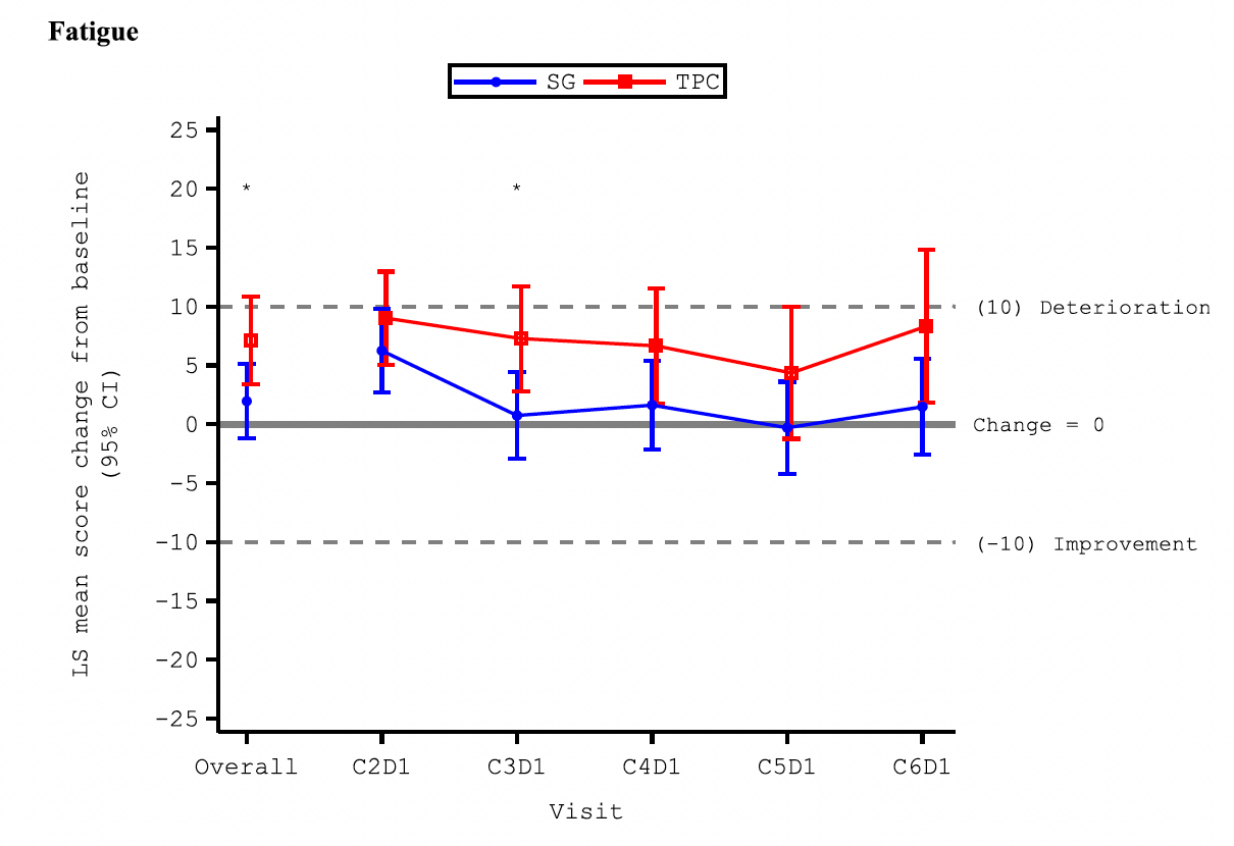
ASCENT: Global Health Status/Quality of Life (QoL) and Physical Functioning

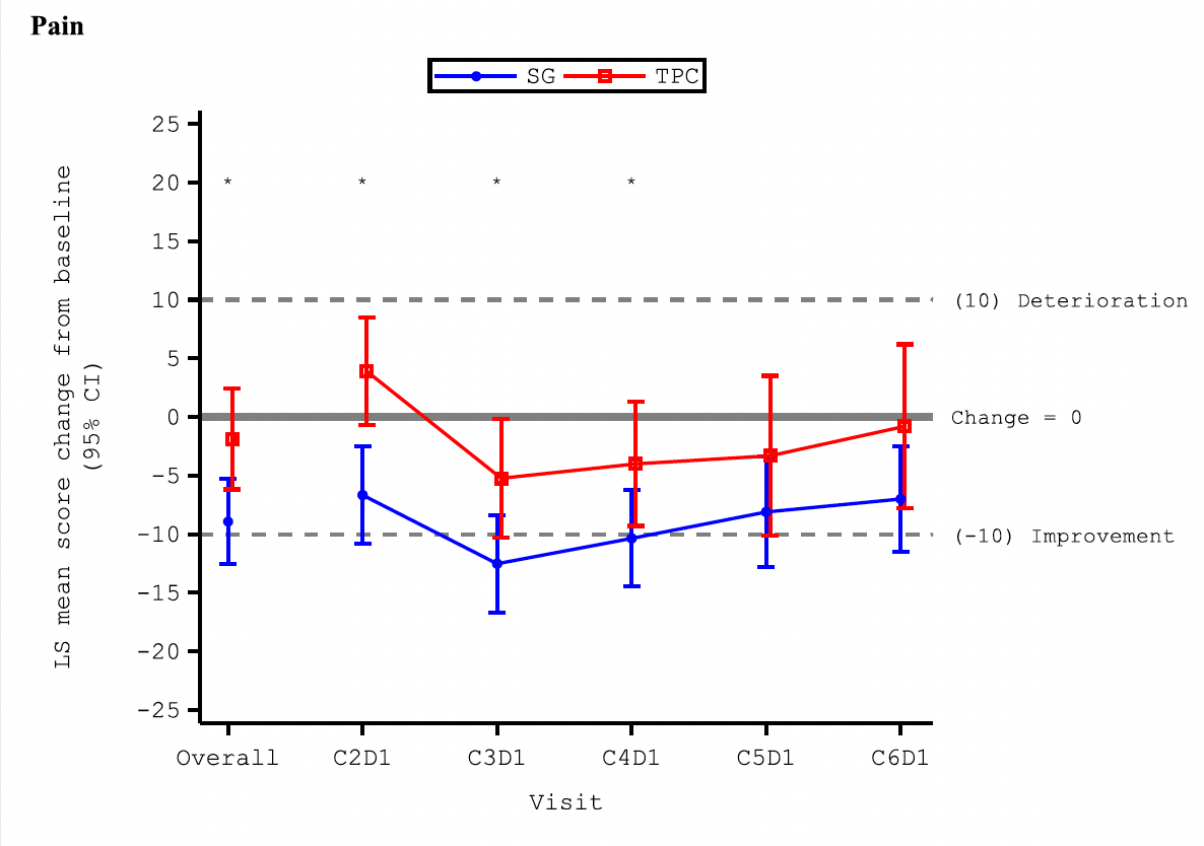




Loibl S et al. *Eur J Cancer* 2023;178:23-33.

ASCENT: Fatigue and Pain





Loibl S et al. *Eur J Cancer* 2023;178:23-33.

ASCENT: Selected Adverse Events

Adverse event	Patients (N = 108)		
	Any grade	Grade 3	Grade 4
Gastrointestinal disorders			
Nausea	67%	6%	0
Diarrhea	62%	8%	0
Vomiting	49%	6%	0
Blood and lymphatic system disorders			
Neutropenia	64%	26%	16%
Anemia	50%	11%	0
Abnormal values			
Decrease white blood cell counts	21%	8%	3%

Bardia A et al. *N Engl J Med* 2021;384:1529-41.

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TROPION-PanTumor01 Trial: Treatment-Emergent Adverse Events (TEAEs) with Dato-DXd in the TNBC Cohort

TEAEs, n (%)	N=44	
	Any grade	Grade ≥3
Any TEAE	**44 (100)**	**23 (52)**
Stomatitis	32 (73)	5 (11)
Nausea	29 (66)	1 (2)
Vomiting	17 (39)	2 (5)
Alopecia	16 (36)	NA
Fatigue	15 (34)	3 (7)
Headache	11 (25)	0
Constipation	10 (23)	0
Decreased neutrophil count	9 (20)	1 (2)
Pyrexia	8 (18)	0
Cough	8 (18)	0
Decreased lymphocyte count	8 (18)	3 (7)
Anemia	7 (16)	1 (2)
Decreased appetite	7 (16)	0
Hypokalemia	7 (16)	0
Diarrhea	7 (16)	0
Rash	7 (16)	0
Dry eye	7 (16)	0

Bardia A et al. SABCS 2022;Abstract P6-10-03.

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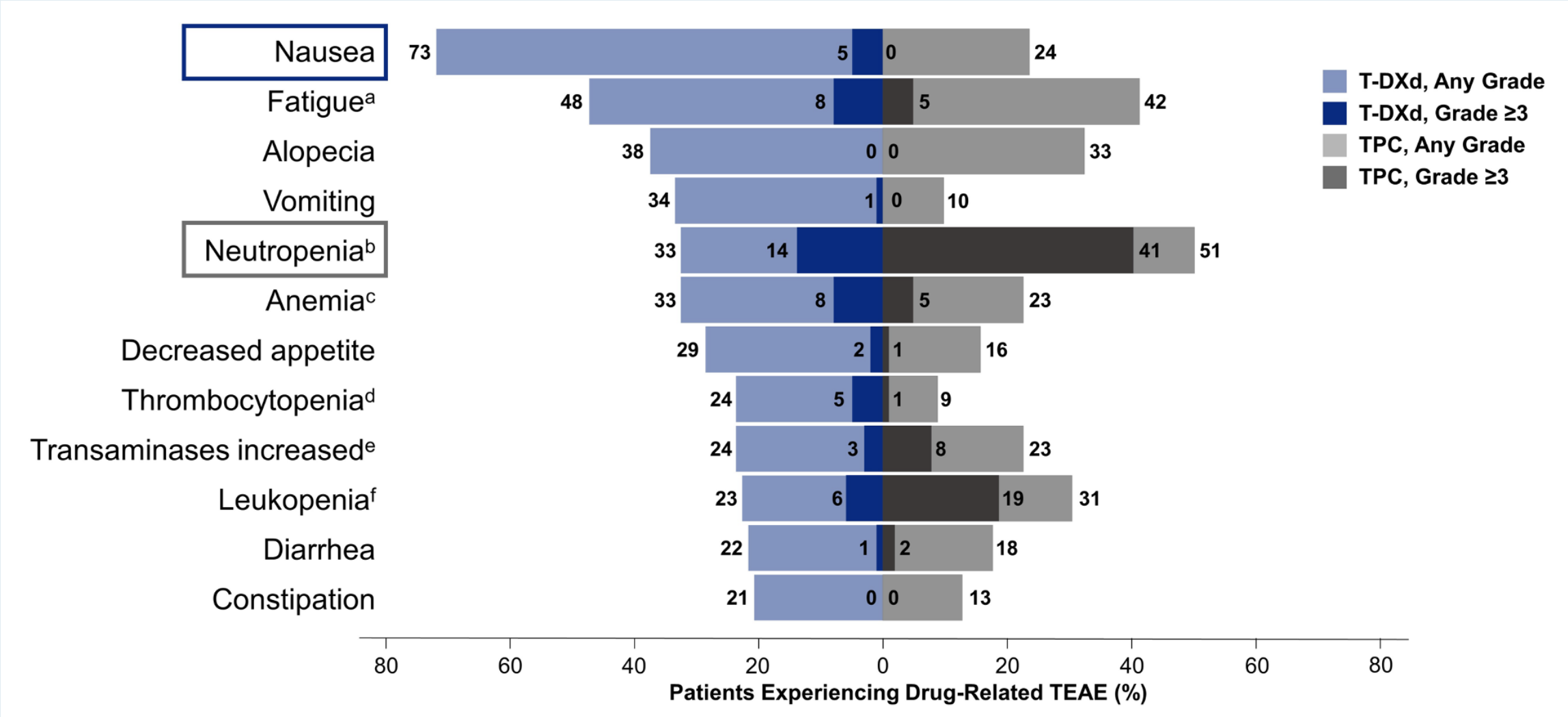
DESTINY-Breast04: Common Drug-Related TEAEs with T-DXd



Modi S et al. ASCO 2022;Abstract LBA3. Modi S et al. *N Engl J Med* 2022;387(1):9-20.

DESTINY-Breast04: Adverse Events of Special Interest

Adjudicated as drug-related ILD/pneumonitis

n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any grade
T-DXd (n = 371)	13 (3.5)	24 (6.5)	5 (1.3)	0	3 (0.8)	45 (12.1)
TPC (n = 172)	1 (0.6)	0	0	0	0	1 (0.6)

Left ventricular dysfuctions

n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any grade
Ejection fraction decreased						
T-DXd (n = 371)	1 (0.3)	12 (3.8)	1 (0.3)	0	0	16 (4.3)
TPC (n = 172)	0	0	0	0	0	0
Cardiac failure						
T-DXd (n = 371)	0	1 (0.3)	1 (0.3)	0	0	2 (0.5)
TPC (n = 172)	0	0	0	0	0	0

ILD = interstitial lung disease; TPC = treatment of physician's choice

Modi S et al. ASCO 2022;Abstract LBA3.

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Meet The Professor: Current and Future Use of Nontargeted Therapy for Metastatic Non-Small Cell Lung Cancer — A 2024 World Conference on Lung Cancer Review

A CME/MOC-Accredited Live Webinar

Tuesday, November 19, 2024
5:00 PM – 6:00 PM ET

Faculty

Heather Wakelee, MD, FASCO

Moderator

Neil Love, MD

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Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

Information on how to obtain CME, ABIM MOC and ABS credit is provided in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

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